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, 2020

OR

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

For the transition period from _____ to_____

Commission File Number: 001-35703

PUMA BIOTECHNOLOGY, INC.

(Exact name of registrant as specified in its charter)

Delaware	**77-0683487**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

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

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

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

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

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

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

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

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

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

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

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date. 39,364,379 shares of Common Stock, par value $0.0001 per share, were outstanding as of May 1, 2020.

PUMA BIOTECHNOLOGY, INC.

- INDEX -

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

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

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

These statements are often, but not always, made through the use of words or phrases such as “anticipate,” “estimate,” “plan,” “project,” “continuing,” “ongoing,” “expect,” “believe,” “intend” and similar words or phrases. Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. Discussions containing these forward-looking statements may be found throughout this Quarterly Report, including, in Part I, the section entitled “Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.” These forward-looking statements involve risks and uncertainties, including the risks discussed in Part I, Item 1A. “Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2019 and in Part II, Item 1A, “Risk Factors” of this Quarterly Report that could cause our actual results to differ materially from those in the forward-looking statements. Such risks should be considered in evaluating our prospects and future financial performance. We undertake no obligation to update the forward-looking statements or to reflect events or circumstances after the date of this document.

Part I – FINANCIAL INFORMATION

Item 1. Financial Statements

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

	March 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 83,385	$ 60,037
Marketable securities	17,170	51,607
Accounts receivable, net	31,542	28,896
Inventory, net	3,297	3,170
Prepaid expenses, current	13,937	13,259
Deferred rent	195	154
Restricted cash, current	8,850	8,850
Other current assets	305	323
Total current assets	158,681	166,296
Lease right-of-use assets, net	18,016	18,522
Property and equipment, net	3,085	3,304
Intangible assets, net	39,474	40,461
Restricted cash, long-term	3,812	4,323
Prepaid expenses and other, long-term	2,461	1,999
Total assets	$ 225,529	$ 234,905
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 17,268	$ 19,183
Accrued expenses	69,464	69,030
Post-marketing commitment liability, current	1,000	—
Lease liabilities, current	2,735	2,624
Total current liabilities	90,467	90,837
Lease liabilities, long-term	21,930	22,643
Post-marketing commitment liability, long-term	8,000	9,000
Long-term debt	95,755	94,962
Total liabilities	216,152	217,442
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Common stock - $.0001 par value per share; 100,000,000 shares authorized; 39,317,221 shares issued and outstanding at March 31, 2020 and 39,203,304 issued and outstanding at December 31, 2019	4	4
Additional paid-in capital	1,303,940	1,295,033
Accumulated other comprehensive income	2	62
Accumulated deficit	(1,294,569)	(1,277,636)
Total stockholders' equity	9,377	17,463
Total liabilities and stockholders' equity	$ 225,529	$ 234,905

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

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

	For the Three Months Ended March 31,	
	2020	2019
Revenue:		
Product revenue, net	$ 48,609	$ 45,567
License revenue	2,000	53,500
Royalty revenue	608	—
Total revenue	51,217	99,067
Operating costs and expenses:		
Cost of sales	9,076	7,985
Selling, general and administrative	30,937	45,506
Research and development	25,455	35,728
Total operating costs and expenses	65,468	89,219
(Loss) profit from operations	(14,251)	9,848
Other income (expenses):		
Interest income	386	872
Interest expense	(3,068)	(4,443)
Legal verdict expense	(93)	(16,350)
Other income (expenses)	93	(14)
Total other expenses	(2,682)	(19,935)
Net loss	$ (16,933)	$ (10,087)
Net loss applicable to common stockholders	$ (16,933)	$ (10,087)
Net loss per share of common stock—basic and diluted	$ (0.43)	$ (0.26)
Weighted-average shares of common stock outstanding—basic and diluted	39,291,162	38,481,824

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

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

	For the Three Months Ended March 31,	
	2020	2019
Net loss	$ (16,933)	$ (10,087)
Other comprehensive loss		
Unrealized (loss) gain on available-for-sale securities, net of tax of $0 and $0	(63)	32
Reclassifications of gain on available-for-sale securities, included in "Other income (expenses)", net of tax of $0 and $0	3	—
Comprehensive loss	$ (16,993)	$ (10,055)

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

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

For the Three Months Ended March 31, 2020

	Common Stock		Additional Paid-in Capital	Receivables from Exercises of Options	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Amount					
Balance at December 31, 2019	39,203,304	$ 4	$ 1,295,033	$ —	$ 62	$ (1,277,636)	$ 17,463
Stock-based compensation	—	—	8,907	—	—	—	8,907
Shares issued or restricted stock units vested under employee stock plans	113,917	—	—	—	—	—	—
Reclassification of gain on available-for-sale securities	—	—	—	—	3	—	3
Unrealized loss on available-for-sale securities	—	—	—	—	(63)	—	(63)
Net loss	—	—	—	—	—	(16,933)	(16,933)
Balance at March 31, 2020	39,317,221	$ 4	$ 1,303,940	$ —	$ 2	$ (1,294,569)	$ 9,377

For the Three Months Ended March 31, 2019

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

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

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

	For the Three Months Ended March 31,	
	2020	**2019**
Operating activities:		
Net loss	$ (16,933)	$ (10,087)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,916	2,135
Stock-based compensation	8,907	18,138
Disposal of property and equipment	—	1
Changes in operating assets and liabilities:		
Accounts receivable, net	(2,646)	(60,211)
Inventory, net	(127)	(12)
Prepaid expenses and other	(1,140)	1,230
Other current assets	18	(8,368)
Accounts payable	(1,928)	8,194
Accrued expenses	434	23,850
Deferred rent	(41)	—
Post-marketing commitment liability	—	9,000
Net cash used in operating activities	(11,540)	(16,130)
Investing activities:		
Purchase of available-for-sale securities	—	(86,715)
Maturity of available-for-sale securities	34,377	42,132
Net cash provided by (used in) investing activities	34,377	(44,583)
Financing activities:		
Net proceeds from shares issued under employee stock plans	—	1,082
Net cash provided by financing activities	—	1,082
Net increase (decrease) in cash, cash equivalents and restricted cash	22,837	(59,631)
Cash, cash equivalents and restricted cash, beginning of period	73,210	112,738
Cash, cash equivalents and restricted cash, end of period	$ 96,047	$ 53,107
Supplemental disclosures of non-cash investing and financing activities:		
Property and equipment purchases in accounts payable	$ 13	$ —
Receivables related to stock option exercises	$ —	$ 11
Supplemental disclosure of cash flow information:		
Interest paid	$ 2,275	$ 3,228

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

Note 1—Business and Basis of Presentation:

Business:

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

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

Basis of Presentation:

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

In February 2020, NERLYNX was also approved by the FDA in combination with capecitabine for the treatment of adult patients with advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting.

In 2018, the European Commission, or EC, granted marketing authorization for NERLYNX in the European Union for the extended adjuvant treatment of adult patients with early stage hormone receptor positive HER2-overexpressed/amplified breast cancer and who are less than one year from the completion of prior adjuvant trastuzumab-based therapy.

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

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

The Company has reported a net loss of approximately $16.9 million and negative cash flows from operations of approximately $11.5 million for the three months ended March 31, 2020. The Company's commercialization, research and development or marketing efforts may require funding in addition to the cash and cash equivalents totaling approximately $83.4 million and marketable securities totaling approximately $17.2 million available at March 31, 2020. The Company believes that its existing cash and cash equivalents and marketable securities as of March 31, 2020 and proceeds that will become available to the Company through product sales and sub-license payments are sufficient to satisfy its operating cash and needs for at least one year after the filing of the Quarterly Report on Form 10-Q in which these financial statements are included. The Company continues to remain dependent on its ability to obtain sufficient funding to sustain operations and continue to successfully commercialize neratinib in the United States. While the Company has been successful in raising capital in the past, there can be no assurance that it will be able to do so in the future. The Company's ability to obtain funding may be adversely impacted by uncertain market conditions, the Company's success in commercializing neratinib, unfavorable decisions of regulatory authorities or adverse clinical trial results. The outcome of these matters cannot be predicted at this time. Additionally, the terms of the Company's loan and security agreement place restrictions on the Company's ability to operate the business and on the Company's financial flexibility, and the Company may be unable to achieve the revenue necessary to satisfy the minimum revenue covenants.

Since its inception through March 31, 2020, the Company's financing has primarily been proceeds from product and license revenue, public offerings of its common stock, private equity placements, and borrowings under its loan and security agreement.

Note 2—Significant Accounting Policies:

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

Principles of Consolidation:

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

Segment Reporting:

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

Use of Estimates:

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

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

Net Loss per Share of Common Stock:

Basic net loss per share of common stock is computed by dividing net loss applicable to common stockholders by the weighted average number of shares of common stock outstanding during the periods presented, as required by Accounting Standards Codification, or ASC, 260, *Earnings per Share*. For purposes of calculating diluted loss per share of common stock, the denominator includes both the weighted average number of shares of common stock outstanding and the number of dilutive common stock equivalents, such as stock options, restricted stock units, or RSUs, and warrants. A common stock equivalent is not included in the denominator when calculating diluted earnings per common share if the effect of such common stock equivalent would be anti-dilutive. For the quarter ended March 31, 2020, potentially dilutive securities excluded from the calculations were 4,330,242 shares issuable upon exercise of options, 2,116,250 shares issuable upon exercise of a warrant, and 2,274,100 shares underlying RSUs that were subject to vesting and were antidilutive. For the quarter ended March 31, 2019, potentially dilutive securities excluded from the calculations were 5,554,070 shares issuable upon exercise of options, 2,116,250 shares issuable upon exercise of a warrant, and 1,698,146 shares underlying RSUs that were subject to vesting and were antidilutive.

Revenue Recognition:

The Company adopted ASC Topic 606, *Revenue from Contracts with Customers*, or ASC 606, on January 1, 2017. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements, and financial instruments. Under ASC 606, an entity recognizes revenue when its customer obtains control of the promised goods or services, in an amount that reflects the consideration which the entity expects to be entitled in exchange for those goods or services. The Company had no contracts with customers until the FDA approved NERLYNX on July 17, 2017. Subsequent to receiving FDA approval, the Company entered into a limited number of arrangements with specialty pharmacies and specialty distributors in the United States to distribute NERLYNX. These arrangements are the Company's initial contracts with customers. The Company has determined that these sales channels with customers are similar.

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 68 days.

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

If taxes should be collected from customers relating to product sales and remitted to governmental authorities, they will be excluded from revenue. The Company expenses incremental costs of obtaining a contract when incurred if the expected amortization period of the asset that the Company would have recognized is one year or less. However, no such costs were incurred during the quarter ended March 31, 2020.

Product revenue from each of the Company's customers who individually accounted for 10% or more of total revenues consisted of the following:

	For the Three Months Ended March 31, 2020
Caremark, LLC	33%
Accredo Health Group, Inc. / AcariaHealth, Inc.	21%
Biologics, Inc.	11%
ASD Healthcare and Oncology Supply	11%

	For the Three Months Ended March 31, 2019
Caremark, LLC	30%
Accredo Health Group, Inc. / AcariaHealth, Inc.	25%
Biologics, Inc.	11%
Diplomat Pharmacy, Inc.	11%

Reserves for Variable Consideration:

Revenue from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established. Components of variable consideration include trade discounts and allowances, product returns, provider chargebacks and discounts, government rebates, payor rebates, and other incentives, such as voluntary patient assistance, and other allowances that are offered within contracts between the Company and its customers, payors, and other indirect customers relating to the Company's sale of its products. These reserves, as detailed below, are based on the related sales, and are classified as reductions of accounts receivable, net or as a current liability. These estimates take into consideration a range of possible outcomes that are probability-weighted in accordance with the expected value method in ASC 606 for relevant factors such as current contractual and statutory requirements, specific known market events and trends, industry data, and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the respective underlying contracts.

The amount of variable consideration that is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. The Company's analyses also contemplated application of the constraint in accordance with the guidance, under which it determined a material reversal of revenue would not occur in a future period for the estimates detailed below as of March 31, 2020 and, therefore, the transaction price was not reduced further during the quarter ended March 31, 2020. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Trade Discounts and Allowances:

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

Product Returns:

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

Provider Chargebacks and Discounts:

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

Government Rebates:

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

Payor Rebates:

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

Other Incentives:

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

License Revenue:

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

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

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

Pint Agreement

During 2018, the Company entered into a sub-license agreement, or the Pint Agreement, with Pint Pharma International SA, or Pint. The Pint Agreement granted intellectual property rights and set forth the respective obligations with respect to development, commercialization and supply of NERLYNX in Mexico and 21 countries and territories in Central and South America, or the Pint Territory. The Pint 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 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. Pursuant to the Pint Agreement, the Company received a non-deductible, non-creditable upfront payment upon providing certain required documents on or before September 30, 2018 to the satisfaction of Pint. During the third quarter of 2018, the Company satisfied this performance obligation, and revenue has been recognized under the terms of the arrangement. The Pint Agreement also includes potential milestone and royalty payments due to the Company upon successful completion of certain performance obligations, such as achieving regulatory approvals, which would entitle the Company to receive payments totaling approximately $24.5 million if all respective performance obligations are achieved. During the third quarter of 2019 and the first quarter of 2020, the Company achieved certain development-based milestones, which satisfied performance obligations necessary to recognize the associated license revenue. The payments associated with this license revenue are included in accounts receivable, net on the consolidated balance sheet as of March 31, 2020. In addition, the Company is entitled to receive double-digit royalties on sales of licensed products, calculated as a percentage of net sales of licensed products throughout the Pint Territory. At this time, the Company cannot estimate if or when the remaining milestone-related performance obligations might be achieved.

Royalty Revenue:

Royalty revenue consists of consideration earned related to international sales of NERLYNX made by the Company's sub-licensees in their respective territories. The Company recognizes royalty revenue when the performance obligations have been satisfied.

Royalties:

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

Research and Development Expenses:

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

In instances where the Company enters into agreements with third parties for clinical trials and other consulting activities, upfront amounts are recorded to prepaid expenses and other in the accompanying consolidated balance sheets and expensed as services are performed or as the underlying goods are delivered. If the Company does not expect the services to be rendered or goods to be delivered, any remaining capitalized amounts for non-refundable upfront payments are charged to expense immediately.

Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments and payments upon the completion of milestones or receipt of deliverables.

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

Stock-Based Compensation:

Stock Option Awards:

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

Restricted Stock Units:

RSUs are valued on the grant date and the fair value of the RSUs is equal to the market price of the Company's common stock on the grant date. The RSU expense is recognized over the requisite service period. When the requisite service period begins prior to the grant date (because the service inception date occurs prior to the grant date), the Company is required to begin recognizing compensation cost before there is a measurement date (i.e., the grant date). The service inception date is the beginning of the requisite service period. If the service inception date precedes the grant date, accrual of compensation cost for periods before the grant date shall be based on the fair value of the award at the reporting date. In the period in which the grant date occurs, cumulative compensation cost shall be adjusted to reflect the cumulative effect of measuring compensation cost based on fair value at the grant date rather than the fair value previously used at the service inception date (or any subsequent reporting date). RSU forfeitures are estimated when the RSU is granted to reduce the RSU expense to be recognized over the life of the award. The estimated forfeiture

rate considers historical employee turnover rates stratified into employee pools, actual forfeiture experience and other factors. The RSU expense is "trued-up" upon the actual forfeiture of a RSU grant and the Company periodically revises the estimated forfeiture rate in subsequent periods if actual forfeitures differ from those estimates. Compensation expense related to modified restricted stock units is measured based on the fair value for the awards as of the modification date. Any incremental compensation expense arising from the excess of the fair value of the awards on the modification date compared to the fair value of the awards immediately before the modification date is recognized at the modification date or ratably over the requisite service period, as appropriate.

Warrants:

Warrants (refer to Note 10 for further details) granted to employees and nonemployees are normally valued at the fair value of the instrument on the grant date and are recognized in the statement of operations over the requisite service period. When the requisite service period precedes the grant date and a market condition exists in the warrant, the Company values the warrant using the Monte Carlo Simulation Method. When the terms of the warrant become fixed, the Company values the warrant using the Black-Scholes Option Pricing Method. As allowed by ASC 718 for companies with a short period of publicly traded stock history, the Company's estimate of expected volatility is based on the average volatilities of a sampling of eight to nine companies with similar attributes to the Company, including industry, stage of life cycle, size and financial leverage. The risk-free rate for periods within the contractual life of the warrant is based on the U.S. Treasury yield curve in effect at the time of grant valuation. In determining the value of the warrant until the terms are fixed, the Company factors in the probability of the market condition occurring and several possible scenarios. When the requisite service period precedes the grant date and is deemed to be complete, the Company records the fair value of the warrant at the time of issuance as an equity stock-based compensation transaction. The grant date is determined when all pertinent information, such as exercise price and quantity are known.

Income Taxes:

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

The standard addresses the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the consolidated financial statements. Under ASC 740, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the tax authorities, based on the technical merits of the position. The tax benefits recognized in the consolidated financial statements from such a position should be measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. ASC 740 also provides guidance on de-recognition, classification, interest and penalties on income taxes, accounting in interim periods and requires increased disclosures. As of March 31, 2020, the Company's uncertain tax position reserves include a reserve for its R&D credits.

Financial Instruments:

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

Cash and Cash Equivalents:

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

Restricted Cash:

Restricted cash represents cash held at financial institutions that are pledged as collateral for stand-by letters of credit for lease and legal verdict commitments. The lease-related letters of credit will lapse at the end of the respective lease terms through 2026. At March 31, 2020 and December 31, 2019, the Company had restricted cash in the amount of $12.7 million and $13.2 million, respectively.

Investment Securities:

The Company classifies all investment securities (short-term and long-term) as available-for-sale, as the sale of such securities may be required prior to maturity to implement management's strategies. These securities are carried at fair value, with the unrealized gains and losses reported as a component of accumulated other comprehensive income 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.

Assets Measured at Fair Value on a Recurring Basis:

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

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

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

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

Following are the major categories of assets measured at fair value on a recurring basis as of March 31, 2020 and December 31, 2019, 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, 2020	Level 1	Level 2	Level 3	Total
Cash equivalents	$ 76,054	$ —	$ —	$ 76,054
Corporate bonds	—	12,133	—	12,133
U.S. government securities	5,037	—	—	5,037
Totals	$ 81,091	$ 12,133	$ —	$ 93,224

December 31, 2019	Level 1	Level 2	Level 3	Total
Cash equivalents	$ 41,295	$ —	$ —	$ 41,295
Corporate bonds	—	41,557	—	41,557
U.S. government securities	10,050	—	—	10,050
Totals	$ 51,345	$ 41,557	$ —	$ 92,902

The Company's investments in corporate bonds and U.S. government securities are exposed to price fluctuations. The fair value measurements for 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, 2020	Maturity (in years)	Amortized cost	Unrealized Gains	Unrealized Losses	Estimated fair value
Cash equivalents		$ 76,054	$ —	$ —	$ 76,054
Corporate bonds	Less than 1	12,135	—	(2)	12,133
U.S. government securities	Less than 1	5,033	4	—	5,037
Totals		$ 93,222	$ 4	$ (2)	$ 93,224

December 31, 2019	Maturity (in years)	Amortized cost	Unrealized Gains	Unrealized Losses	Estimated fair value
Cash equivalents		$ 41,295	$ —	$ —	$ 41,295
Corporate bonds	Less than 1	41,507	50	—	$ 41,557
U.S. government securities	Less than 1	10,038	12	—	$ 10,050
Totals		$ 92,840	$ 62	$ —	$ 92,902

Concentration of Risk:

Financial instruments, which potentially subject the Company to concentrations of credit risk, principally consist of cash and cash equivalents, marketable securities, and accounts receivable, net. The Company's cash and cash equivalents and restricted cash in excess of the Federal Deposit Insurance Corporation and the Securities Investor Protection Corporation insured limits at March 31, 2020, were approximately $98.6 million. The Company does not believe it is exposed to any significant credit risk due to the quality nature of the financial instruments in which the money is held. Pursuant to the Company's internal investment policy, investments must be rated A-1/P-1 or better by Standard and Poor's Rating Service and Moody's Investors Service at the time of purchase.

The Company sells its products in the United States primarily through specialty pharmacies and specialty distributors. Therefore, wholesale distributors and large pharmacy chains account for a large portion of its accounts receivables, net and product revenues, net. The creditworthiness of its customers is continuously monitored, and the Company has internal policies regarding customer credit limits. The Company estimates an allowance for doubtful accounts primarily based on the credit worthiness of its customers, historical payment patterns, aging of receivable balances and general economic conditions. The Company recorded $0 as an allowance for doubtful accounts in the three months ended March 31, 2020 and 2019.

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

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

Inventory:

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

The Company capitalizes inventory costs associated with the Company's products after regulatory approval, if any, when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. Inventory totaling $4.5 million, acquired prior to receipt of marketing approval of a product candidate, was recorded as research and development expense in the year ended December 31, 2017. 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 selling, general and administrative expense as incurred.

As of March 31, 2020, the Company's inventory balance consisted primarily of raw materials purchased subsequent to FDA approval of NERLYNX.

Property and Equipment, Net:

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

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

Leases:

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

Leases will be classified as financing or operating, which will drive the expense recognition pattern. The Company elects to exclude short-term leases if and when the Company has them. For additional information, see Note 5—Leases.

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

The incremental borrowing rate, or IBR, represents the rate of interest that the Company would expect to pay on a collateralized basis to borrow an amount equal to the lease payments under similar terms. When determinable, the Company uses the rate implicit in the lease to determine the present value of lease payments. As the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. The Company's average IBR for existing leases as of March 31, 2020 is 10.9%.

The Company decided to cease the use of a portion of its leased office space in 2019. In connection with the decreased need for the right to use the ROU asset, the Company entered into a sublease for the underlying asset, in which the sublease income is less than the original lease payments, indicating impairment. In performing the recoverability test on the effective date, the undiscounted future estimated cash flows and carrying value were identified for the subleased portion of the leased building, as an individual asset group, defined under ASC 360. A reduction to the carrying value of the ROU asset was recorded of approximately $1.2 million representing the fair value amount in excess of the carrying value, with a corresponding impairment charge recorded as selling, general and administration expense, in the consolidated statements of operations for the year ended December 31, 2019. There were no indications for impairment during the quarter ended March 31, 2020.

License Fees and Intangible Assets:

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

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

The Company assesses its intangible assets for impairment if indicators are present or changes in circumstance suggest that impairment may exist. Events that could result in an impairment, or trigger an interim impairment assessment, include the receipt of additional clinical or nonclinical data regarding one of the Company's drug candidates or a potentially competitive drug candidate, changes in the clinical development program for a drug candidate, or new information regarding potential sales for the drug. If impairment indicators are present or changes in circumstance suggest that impairment may exist, the Company performs a recoverability test by comparing the sum of the estimated undiscounted cash flows of each intangible asset to its carrying value on the consolidated balance sheet. If the undiscounted cash flows used in the recoverability test are less than the carrying value, the Company would determine the fair value of the intangible asset and recognize an impairment loss if the carrying value of the intangible asset exceeds its fair value. In connection with the FDA approval of NERLYNX in July 2017, the Company triggered a one-time milestone payment pursuant to its license agreement with Pfizer. The Company capitalized the milestone payment as an intangible asset and is amortizing the asset to cost of sales on a straight-line basis over the estimated useful life of the licensed patent through 2030. The Company recorded amortization expense related to its intangible asset of $1.0 million for both the three months ended March 31, 2020 and 2019. As of March 31, 2020, estimated future amortization expense related to the Company's intangible asset was approximately $2.9 million for the remainder of 2020 and $3.9 million for each year starting 2021 through 2029, and $1.0 million for 2030.

Recently Issued Accounting Standards:

In June 2016, the FASB issued ASU 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. ASU 2016-13 requires that credit losses be reported using an expected losses model rather than the incurred losses model that is currently used, and establishes additional disclosures related to credit risks. For available-for-sale debt securities with unrealized losses, this standard now requires allowances to be recorded instead of reducing the amortized cost of the investment. These amendments under ASU 2016-13 are effective for interim and annual fiscal periods beginning after December 15, 2019. The adoption of ASU 2016-13 did not have a material effect on the Company's current financial position, results of operations or financial statement disclosures.

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement. The amendments in ASU 2018-13 modifies the disclosure requirements on fair value measurements. ASU 2018-13 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted for any removed or modified disclosures. The amendments did not have an impact on the Company's financial statement disclosures.

In December 2019, the FASB issued ASU No 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes, as part of its Simplification Initiative to reduce the cost and complexity in accounting for income taxes. The amendments in ASU 2019-12 removes certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. ASU 2019-12 also

amends other aspects of the guidance to help simplify and promote consistent application of GAAP. The guidance is effective for interim and annual periods beginning after December 15, 2020, with early adoption permitted. The Company does not expect ASU 2019-12 to have a material effect on the Company's current financial position, results of operations or financial statement disclosures.

Note 3—Accounts Receivable, Net:

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

	March 31, 2020	December 31, 2019
Accounts receivable, net	$ 27,042	$ 26,396
License revenue receivable	4,500	2,500
Total accounts receivable, net	$ 31,542	$ 28,896

Accounts receivable, net, consists entirely of amounts owed from our customers related to product sales. The license revenue receivable relates to amounts owed from Pint relating to license revenue recognized during the third quarter of 2019 and the first quarter of 2020.

Note 4—Prepaid Expenses and Other:

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

	March 31, 2020	December 31, 2019
Current:		
CRO services	$ 4,118	$ 4,810
Other clinical development	3,187	2,043
Insurance	2,502	3,452
Professional fees	1,127	544
Other	3,003	2,410
	13,937	13,259
Long-term:		
CRO services	376	400
Other clinical development	476	468
Other	1,609	1,131
	2,461	1,999
Totals	$ 16,398	$ 15,258

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

Note 5—Leases:

In December 2011, the Company entered into a non-cancelable operating lease for office space in Los Angeles, California, which was subsequently amended in November 2012, December 2013, March 2014 and July 2015, and December 2017. The initial term of the lease was for seven years and commenced on December 10, 2011. As amended, the Company rents approximately 65,656 square feet. The term of the lease runs until March 2026, and rent amounts payable by the Company increase approximately 3% per year. Concurrent with the execution of the lease, the Company provided the landlord an automatically renewable stand-by letter of credit in the amount of $2.5 million. The stand-by letter of credit is collateralized by a high-yield savings account, which is classified as restricted cash, long-term on the accompanying consolidated balance sheets.

In June 2012, the Company entered into a long-term lease agreement for office space in South San Francisco, California, which was subsequently amended in May 2014 and July 2015. As amended, the Company rents approximately 29,470 square feet. The term of this lease runs until March 2026, with the option to extend for an additional five-year term, and rents payable by the Company increase approximately 3% per year. The Company provided the landlord an automatically renewable stand-by letter of credit in the amount of $1.6 million. The stand-by letter of credit is collateralized by a high-yield savings account, which is classified as restricted cash, long-term on the accompanying consolidated balance sheets.

The Company also leases copier equipment for use in the office spaces. Components of lease expense include fixed lease expense and variable lease expense of approximately $1.2 million and $0.1 million, respectively, for the three months ended March 31, 2020. Fixed and variable lease expense for the quarter ended March 31, 2019, was approximately $1.2 million and $0.1 million, respectively. For purposes of determining straight-line rent expense, the lease term is calculated from the date the Company first takes possession of the facility, including any periods of free rent and any renewal option periods that the Company is reasonably certain of exercising. The Company's office and equipment leases generally have contractually specified minimum rent and annual rent increases that are included in the measurement of the ROU asset and related lease liability. Additionally, under these lease arrangements, the Company may be required to pay directly, or reimburse the lessors, for real estate taxes, insurance, utilities, maintenance and other operating costs. Such amounts are generally variable and therefore not included in the measurement of the ROU asset and related lease liability but are instead recognized as variable lease expense in selling, general and administrative costs in the consolidated statements of operations when they are incurred.

Supplemental cash flow information related to leases for the three months ended March 31, 2020:

Operating cash flows for operating leases (in thousands)	$	1,400
Right-of-use assets obtained in exchange for new operating lease liabilities		—
Weighted average remaining lease term (in years)		6.0
Weighted average discount rate		10.9%

The maturity of lease liabilities as of March 31, 2020 were as follows (in thousands):

		Amount
2020 (remaining)	$	3,933
2021		5,365
2022		5,483
2023		5,631
2024		5,805
Thereafter		7,490
Total	$	33,707
Less: imputed interest		(9,042)
Total lease liabilities	**$**	**24,665**

In February 2019, the Company entered into a long-term sublease agreement for 12,429 square feet of the office space in Los Angeles, CA. The term of the lease runs until March 2026 and rent amounts payable to the Company increase approximately 3% per year. The Company recorded operating sublease income of $0.1 million for the three months ended March 31, 2020 in other income (expenses) in the consolidated statements of operations.

The future minimum lease payments to be received as of March 31, 2020 were as follows (in thousands):

		Amount
2020 (remaining)	$	341
2021		467
2022		481
2023		495
2024		510
Thereafter		659
Total	**$**	**2,953**

Note 6—Property and Equipment, Net:

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

	March 31, 2020	December 31, 2019
Leasehold improvements	$ 3,779	$ 3,779
Computer equipment	2,698	2,698
Telephone equipment	340	340
Furniture and fixtures	2,360	2,346
	9,177	9,163
Less: accumulated depreciation	(6,092)	(5,859)
Totals	$ 3,085	$ 3,304

For the three months ended March 31, 2020 and 2019, the Company incurred depreciation expense of $0.2 million and $0.2 million, respectively.

Note 7—Intangible Assets, Net:

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

	March 31, 2020	Estimated Useful Life
Acquired and in-licensed rights	$ 50,000	13 Years
Less: accumulated amortization	(10,526)	
Total intangible asset, net	$ 39,474	

For the three months ended March 31, 2020 and 2019, the Company incurred amortization expense of $1.0 million and $1.0 million, respectively.

Note 8—Accrued Expenses:

Accrued expenses consisted of the following (in thousands):

	March 31, 2020	December 31, 2019
Accrued legal verdict expense	$ 31,443	$ 31,350
Accrued royalties	7,783	8,866
Accrued CRO services	6,811	8,502
Accrued variable consideration	9,709	7,978
Accrued bonus	2,271	1,618
Accrued compensation	4,196	4,138
Accrued other clinical development	2,044	2,546
Accrued professional fees	1,940	1,775
Accrued legal fees	646	266
Accrued manufacturing costs	1,327	869
Other	1,294	1,122
Totals	$ 69,464	$ 69,030

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

Accrued legal verdict expense represents an estimate of a range between $9.1 million and $18.1 million that may be owed to class action participants as a result of the recent jury verdict in *Hsu v. Puma Biotechnology, Inc.,* and an initial estimate of $22.4 million that may be owed to the plaintiff as a result of the recent jury verdict in *Eshelman v. Puma Biotechnology, Inc., et al.* The total amount of damages in *Hsu* and *Eshelman* is uncertain and will be ascertained only after an extensive claims process in *Hsu,* and the completion of post-trial proceedings, and the exhaustion of any appeals in both cases. It is also reasonably possible that the total damages will be higher than these estimates.

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

Note 9—Debt:

Long term debt consisted of the following at March 31, 2020 (in thousands):

	March 31, 2020	Maturity Date
Long-term debt	$ 100,000	June 1, 2024
Accretion of final interest payment	2,260	
Less: deferred financing costs	(6,505)	
Total long-term debt, net	$ 95,755	

In October 2017, the Company entered into a loan and security agreement with Silicon Valley Bank, or SVB, as administrative agent, and the lenders party thereto from time to time, or the Original Lenders, including Oxford Finance LLC, or Oxford, and SVB. Pursuant to the terms of the credit facility provided for by the loan and security agreement, or the Original Credit Facility, the Company borrowed $50.0 million.

In May 2018, the Company entered into an amendment to the loan and security agreement, which provided for an amended credit facility, or the Amended Credit Facility. Under the Amended Credit Facility, the Original Lenders agreed to make term loans available to the Company in an aggregate amount of $155.0 million, consisting of (i) an aggregate amount of $125.0 million, the proceeds of which, in part, were used to repay the $50.0 million borrowed under the Original Credit Facility, and (ii) an aggregate amount of $30.0 million that the Company drew in December 2018, which was available under the Amended Credit Facility as a result of achieving a specified minimum revenue milestone. The Company was in compliance with all applicable financial covenants during the entire term of the Amended Credit Facility.

Prior to the amendment and restatement of the loan and security agreement in June 2019, which provided for a new credit facility, or the New Credit Facility, the term loans under the Amended Credit Facility bore interest at an annual rate equal to the greater of (i) 8.25% and (ii) the sum of (a) the "prime rate," as reported in The Wall Street Journal on the last business day of the month that immediately preceded the month in which the interest accrued, plus (b) 3.5%. The Company was required to make monthly interest-only payments on each term loan commencing on the first calendar day of the calendar month following the funding date of such term loan, and continuing on the first calendar day of each calendar month thereafter through July 1, 2020. Commencing on July 1, 2020, and continuing on the first calendar day of each calendar month thereafter, the Company would have been required to make consecutive equal monthly payments of principal, together with applicable interest, in arrears to each original lender, calculated pursuant to the Amended Credit Facility. All unpaid principal and accrued and unpaid interest with respect to each term loan would have been due and payable in full on May 1, 2023. Upon repayment of the term loans, the Company was also required to make a final payment to the Original Lenders equal to 7.5% of the original principal amount of term loans funded.

The Company was also permitted to prepay the outstanding principal balance of any term loan under the Amended Credit Facility, in whole but not in part, subject to a prepayment fee of 3.0% of any amount prepaid if the prepayment were to occur through and including the first anniversary of the funding date of such term loan, 2.0% of any amount prepaid if the prepayment were to occur after the first anniversary of the funding date of such term loan through and including the second anniversary of the funding date of such term loan, and 1.0% of the amount prepaid if the prepayment were to occur after the second anniversary of the funding date of such term loan and prior to May 1, 2023.

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

The New Credit Facility is secured by substantially all of the Company's personal property other than its intellectual property. The Company also pledged 65% of the issued and outstanding capital stock of its subsidiaries, Puma Biotechnology Ltd. and Puma Biotechnology B.V. The New 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 New Credit Facility bear interest at an annual rate equal to the greater of (i) 9.0% and (ii) the sum of (a) the "prime rate," as reported in The Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 3.5%. The Company is required to make monthly interest-only payments on each term loan under the New Credit Facility commencing on the first calendar day of the calendar month following the funding date of such term loan, and continuing on the first calendar day of each calendar month thereafter through August 1, 2021 or, the Amortization Date. Commencing on the Amortization Date, and continuing on the first calendar day of each calendar month thereafter, the Company will make consecutive equal monthly payments of principal, together with applicable interest, in arrears to each lender under the New Credit Facility, calculated pursuant to the New Credit Facility. All unpaid principal and accrued and unpaid interest with respect to each term loan under the New Credit Facility is due and payable in full on June 1, 2024, or the Maturity Date. Upon repayment of such term loans, the Company is also required to make a final payment to the lenders equal to 7.5% of the aggregate principal amount of such term loans outstanding as of the Effective Date.

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

The New Credit Facility includes affirmative and negative covenants applicable to the Company, its current subsidiaries and any subsidiaries the Company creates in the future. The affirmative covenants include, among others, covenants requiring the Company to maintain its legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and satisfy certain requirements regarding deposit accounts. The Company must also achieve certain product revenue targets, measured as of the last day of each fiscal quarter on a trailing year to date basis. New minimum revenue levels will be established for each subsequent fiscal year by mutual agreement of the Company, Oxford, as collateral agent, and the lenders under the New Credit Facility. The negative covenants 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 New 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 Oxford, as collateral agent, with the right to exercise remedies against the Company and the collateral securing the New Credit Facility, including foreclosure against the property securing the New Credit Facility, including the Company's cash. These events of default include, among other things, the Company's failure to pay principal or interest due under the New Credit Facility, a breach of certain covenants under the New Credit Facility, the Company's insolvency, a material adverse change, the occurrence of any default under certain other indebtedness in an amount greater than $500,000 and one or more judgments against the Company in an amount greater than $500,000 individually or in the aggregate that remains unsatisfied, unvacated, or unstayed for a period of 10 days after its entry.

As of March 31, 2020, there was $100.0 million in term loans outstanding under the New Credit Facility, representing all of the Company's long-term debt outstanding as of that date, and the Company was in compliance with all applicable covenants under the New Credit Facility.

The future minimum principal payments under the New Credit Facility as of March 31, 2020 were as follows (in thousands):

	Amount
2020 (remaining)	$ —
2021	14,286
2022	34,286
2023	34,286
2024	17,142
Thereafter	—
Total	**$ 100,000**

Note 10—Stockholders' Equity:

Common Stock:

The Company issued 500 and 56,125 shares of common stock upon exercise of stock options during the three months ended March 31, 2020 and 2019, respectively. The Company issued 113,417 and 192,912 shares of common stock upon vesting of RSUs during the three months ended March 31, 2020 and 2019, respectively.

Authorized Shares:

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

Warrants:

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

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

Stock Options and Restricted Stock Units:

The Company's 2011 Incentive Award Plan, as amended, or the 2011 Plan, was adopted by the Company's board of directors on September 15, 2011. Pursuant to the 2011 Plan, the Company may grant incentive stock options and nonqualified stock options, as well as other forms of equity-based compensation. Incentive stock options may be granted only to employees, while consultants, employees, officers and directors are eligible for the grant of nonqualified options under the 2011 Plan. The maximum term of stock options granted under the 2011 Plan is 10 years and the awards generally vest over a three-year period. The exercise price of incentive stock options granted under the 2011 Plan must be at least equal to the fair value of such shares on the date of grant. Through March 31, 2020, a total of 12,529,412 shares of the Company's common stock had been reserved for issuance under the 2011 Plan.

All of the options awarded by the Company have been "plain vanilla options" as determined by the SEC Staff Accounting Bulletin 107, or *Share Based Payment.* As of March 31, 2020, 6,539,932 shares of the Company's common stock are issuable upon the exercise of outstanding awards granted under the 2011 Plan and 2,070,707 shares of the Company's common stock are available for future issuance under the 2011 Plan. The fair value of options granted to employees and nonemployees was estimated using the Black-Scholes Option Pricing Method (see Note 2) with the following weighted-average assumptions used during the three months ended March 31:

	2020	2019
Dividend yield	0.0%	0.0%
Expected volatility	102.7%	99.9%
Risk-free interest rate	1.0%	2.5%
Expected life in years	5.80	5.76

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 and the awards generally vest over a three-year period. The exercise price of stock options granted under the 2017 Plan must be at least equal to the fair market value of such shares on the date of grant. As of March 31, 2020, a total of 2,000,000 shares of the Company's common stock have been reserved for issuance under the 2017 Plan. As of March 31, 2020, 1,096,155 shares have been awarded under the 2017 Plan.

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

	For the Three Months Ended March 31,	
	2020	2019
Stock-based compensation:		
Options -		
Selling, general, and administrative	$ 920	$ 2,986
Research and development	841	2,333
Restricted stock units -		
Selling, general, and administrative	3,772	6,889
Research and development	3,374	5,930
Total stock-based compensation expense	$ 8,907	$ 18,138

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, 2019	5,042,325	$ 82.42	5.2	$ 1,951
Granted	606,800	$ 9.96	9.9	
Forfeited	-	$ -		
Exercised	(500)	$ 3.75		$ 5
Expired	(286,638)	$ 84.66		
Outstanding at March 31, 2020	5,361,987	$ 74.10	5.6	$ 1,974
Nonvested at March 31, 2020	975,127	$ 14.66	9.6	
Exercisable	4,386,860	$ 87.32	4.7	$ 1,635

At March 31, 2020, total estimated unrecognized employee compensation cost related to non-vested stock options granted prior to that date was approximately $10.4 million, which is expected to be recognized over a weighted-average period of 2.1 years. At March 31, 2020, the total estimated unrecognized employee compensation cost related to non-vested RSUs was approximately $35.5 million, which is expected to be recognized over a weighted-average period of 1.6 years. The weighted-average grant date fair value of options granted during the three months ended March 31, 2020 and 2019 was $7.86 and $21.82 per share, respectively. The weighted average grant date fair value of RSUs awarded during the three months ended March 31, 2020 and 2019 was $10.74 and $28.69 per share, respectively.

Stock Option Rollforward

	Shares	Weighted Average Grant-Date Fair Value
Nonvested shares at December 31, 2019	439,194	19.38
Granted	606,800	7.86
Vested/Issued	(70,867)	29.61
Forfeited	-	-
Nonvested shares at March 31, 2020	975,127	$ 11.47

Restricted Stock Unit Rollforward

	Shares	Weighted Average Grant-Date Fair Value
Nonvested shares at December 31, 2019	1,991,125	$ 27.63
Granted	626,073	10.74
Vested/Issued	(113,417)	48.96
Forfeited	(229,681)	28.34
Nonvested shares at March 31, 2020	2,274,100	$ 21.85

Note 11—401(k) Savings Plan:

During 2012, the Company adopted a 401(k) savings plan for the benefit of its employees. The Company is required to make matching contributions to the 401(k) plan equal to 100% of the first 3% of wages deferred by each participating employee and 50% on the next 2% of wages deferred by each participating employee. The Company incurred expenses for employer matching contributions of approximately $0.4 million and $0.4 million for the three months ended March 31, 2020 and 2019, respectively.

Note 12—Commitments and Contingencies:

Contractual Obligations:

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

License Agreement:

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

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

As consideration for the license, the Company is required to make substantial payments upon the achievement of certain milestones totaling approximately $187.5 million if all such milestones are achieved. In connection with the FDA approval of NERLYNX in July of 2017, the Company triggered a one-time milestone payment pursuant to the agreement. Additionally, the Company may trigger a one-time milestone payment related to the commercialization efforts in certain European countries. Should the Company commercialize any more of the compounds licensed from Pfizer or any products containing any of these compounds, the Company will be obligated to pay to Pfizer annual royalties at a fixed rate in the low-to-mid teens of net sales of all such products, subject to certain reductions and offsets in some circumstances. The Company's royalty obligation continues, on a product-by-product and country-by-country basis, until the later of (1) the last to expire licensed patent covering the applicable licensed product in such country, or (2) the earlier of generic competition for such licensed product reaching a certain level in such country or expiration of a certain time period after first commercial sale of such licensed product in such country. In the event that the Company sublicenses the rights granted to the Company under the license agreement with Pfizer to a third party, the same milestone and royalty payments are required. The Company can terminate the license agreement at will, or for safety concerns, in each case upon specified advance notice.

Legal Proceedings:

The Company and certain of its executive officers were named as defendants in the lawsuits detailed below. The Company records a liability in the consolidated financial statements for loss contingencies when a loss is known or considered probable and the amount can be reasonably estimated. If the reasonable estimate of a known or probable loss is a range, and no amount within the range is a better estimate than any other, the minimum amount of the range is accrued. If a loss is reasonably possible but not known or probable, and can be reasonably estimated, the estimated loss or range of loss is disclosed. When determining the estimated loss or range of loss, significant judgment is required to estimate the amount and timing of a loss to be recorded. Currently, the Company has accrued estimated losses of $9.1 million related to *Hsu v. Puma Biotechnology, Inc.* and $22.4 million related to *Eshelman v. Puma Biotechnology, Inc., et al.* as detailed below. For certain legal expenses related to the verdicts listed below, the Company has received reimbursements from its insurers.

Hsu v. Puma Biotechnology, Inc.

On June 3, 2015, Hsingching Hsu, individually and on behalf of all others similarly situated, filed a class action lawsuit against the Company and certain of its executive officers in the United States District Court for the Central District of California (Case No. 8:15-cv-00865-AG-JCG). On October 16, 2015, lead plaintiff Norfolk Pension Fund filed a consolidated complaint on behalf of all persons who purchased the Company's securities between July 22, 2014 and May 29, 2015. A trial on the claims relating to four statements alleged to have been false or misleading was held from January 15, 2019 to January 29, 2019. At trial, the jury found that three of the four challenged statements were not false or misleading, and thus found in the defendants' favor on those claims. The jury found liability as to one statement and awarded a maximum of $4.50 per share in damages, which represents approximately 5% of the total claimed damages of $87.20 per share. Trading models suggest that approximately ten million shares traded during the class period may be eligible to claim damages. Based on prior lawsuits, the Company believes that the number of stockholders who submit proof of claims sufficient to recover damages is typically in the range of 20% to 40% of the total eligible shares. Based on these assumptions, total damages after claims could range from $9.0 million to $18.0 million. The total amount of aggregate class-wide damages remains uncertain and will be ascertained only after an extensive claims process and the exhaustion of any appeals and it is reasonably possible that the total damages will be higher than this estimate; however, the amount is not estimable at this time.

On September 9, 2019, the Court entered an order specifying the rate of prejudgment interest to be awarded on any valid claims at the 52-week Treasury Bill rate. The Court's order also established a claims process, which is expected to take about twelve months. A final judgment has not been entered. Based on the final total damages, the Company may owe a success-based legal fee to the Company's legal counsel in the amount of $3.0 million. As the total damages remains uncertain, no liability has been recorded for the legal fee. The Company recognizes legal fees in connection with a loss contingency as incurred.

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

In February 2016, Fredric N. Eshelman filed a lawsuit against the Company's Chief Executive Officer and President, Alan H. Auerbach, and the Company in the United States District Court for the Eastern District of North Carolina (Case No. 7:16-cv-00018-D). The complaint generally alleged that Mr. Auerbach and the Company made defamatory statements regarding Dr. Eshelman in connection with a proxy contest. In May 2016, Dr. Eshelman filed a notice of voluntary dismissal of the claims against Mr. Auerbach. A trial on the remaining defamation claims against the Company took place from March 11 to March 15, 2019. At trial, the jury found the Company liable and awarded Dr. Eshelman $15.9 million in compensatory damages and $6.5 million in punitive damages. The Company strongly disagrees with the verdict and, on April 22, 2019, filed a motion for a new trial or, in the alternative, a reduced damages award. The Court denied that motion on March 2, 2020. The Company has appealed that ruling, and the verdict. Additionally, after trial, the plaintiff filed a motion seeking approximately $3 million in attorneys' fees, as well as prejudgment interest. In the Court's March 2 ruling, it denied the motion for attorneys' fees but granted the request for prejudgment interest, bringing the total judgment to $26.3 million. On March 30, 2020, the plaintiff filed a notice of cross-appeal and conditional cross-appeal, appealing the Court's order denying the plaintiff's request for attorneys' fees and conditionally cross-appealing a Court ruling that certain communications between Mr. Auerbach and his attorneys were protected by attorney-client privilege and a related evidentiary ruling. The Company estimates the high end of potential damages in the matter could be approximately $27.2 million; however, the actual amount of damages payable by the Company is still uncertain and will be ascertained only after completion of the appeal and any subsequent proceedings, and such amount could be greater than the amount of expense already recognized or the high end of the estimate. Due to the appeal, the Company secured a bond for the potential damages, which is collateralized by an automatically renewable stand-by letter of credit in the amount of $8.9 million. The stand-by letter of credit is collateralized by a high-yield savings account which is classified as restricted cash, current on the accompanying consolidated balance sheets.

Note 13—Subsequent Events:

COVID-19 Pandemic:

There are many uncertainties regarding the current global pandemic involving a novel strain of coronavirus, or COVID-19, and the Company is closely monitoring the impact of the pandemic on all aspects of its business, including how it will impact its customers, employees, suppliers, vendors, business partners and distribution channels. The Company is unable to predict the impact that COVID-19 will have on its financial position and operating results due to numerous uncertainties. The Company expects to continue to assess the evolving impact of the COVID-19 pandemic and intends to make adjustments to its responses accordingly.

Paycheck Protection Program Loan:

On April 20, 2020, the Company received loan proceeds from SVB of $8.4 million under the Paycheck Protection Program, or PPP, of the Coronavirus Aid, Relief, and Economic Security Act. Following the issuance of additional guidance from the U. S. Small Business Administration regarding eligibility requirements for borrowers under the PPP, the Company returned the full amount of the loan to SVB on April 30, 2020.

Mainland China Marketing Approval:

On April 27, 2020, the Company's sub-licensee, CANbridge Limited, received marketing approval of NERLYNX (neratinib) in mainland China from the National Medical Products Administration of China for the extended adjuvant treatment of adult patients with early stage HER2 positive breast cancer, to follow adjuvant trastuzumab-based therapy.

Bixink Agreement:

On April 28, 2020, the Company entered into a sub-license agreement, or the Bixink Agreement, with Bixink Therapeutics. Pursuant to the Bixink Agreement, the Company granted to Bixink, under certain of the Company's intellectual property rights relating to neratinib, an exclusive, sublicensable (under certain circumstances) license (i) to develop and commercialize any product containing neratinib and certain related compounds in South Korea, or the Bixink Territory and (ii) to seek and maintain regulatory approvals for the licensed products in the Bixink Territory. Pursuant to the Bixink Agreement, the Company will receive upfront and milestone payments of up to $6 million, each milestone payment payable upon the achievement of the milestone event specified in the Bixink Agreement. In addition, the Company is entitled to receive double digit royalties calculated as a percentage of net sales of the licensed products in the Bixink Territory.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and the notes thereto included in Item 1 in this Quarterly Report on Form 10-Q, or this Quarterly Report. The following discussion should also be read in conjunction with our audited consolidated financial statements and the notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K for the year ended December 31, 2019.

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

Overview

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

Prior to 2017, our efforts and resources had been focused primarily on acquiring and developing our pharmaceutical technologies, raising capital and recruiting personnel. In 2017, the United States Food and Drug Administration, or FDA, approved NERLYNX, formally known as PB272 (neratinib (oral)), for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer following adjuvant trastuzumab-based therapy. In February 2020, NERLYNX was also approved by the FDA in combination with capecitabine for the treatment of adult patients with advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting. In 2018, the European Commission, or EC, granted marketing authorization for NERLYNX in the European Union for the extended adjuvant treatment of adult patients with early stage hormone receptor positive HER2-overexpressed/amplified breast cancer and who are less than one year from the completion of prior adjuvant trastuzumab-based therapy.

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

Our expenses to date have been related to hiring staff, commencing company-sponsored clinical trials and the build out of our corporate infrastructure and, since 2017, the commercial launch of NERLYNX. To date, our major sources of working capital have been proceeds from product and license revenue, public offerings of our common stock, proceeds from our credit facility and sales of our common stock in private placements.

Impact of COVID-19

Our priorities during the COVID-19 pandemic are protecting the health and safety of our employees while continuing our mission to develop and commercialize innovative products to enhance cancer care. Many geographic regions have imposed, or in the future may impose, "shelter-in-place" orders, quarantines or similar orders or restrictions to control the spread of COVID-19. These types of restrictions may deter or prevent cancer patients from traveling to see their doctors and result in a decline in revenue for NERLYNX, our only commercial product. Additionally, our commercial team and sales force have suspended travel and personal interactions with physicians and customers, including visits to healthcare provider officers, and are currently limited to conducting promotional activities virtually. The respective commercial teams of certain of the companies to which we sub-license the commercial rights of NERLYNX, and on which we rely for our international sales, have chosen or have been forced to take similar action, and other sub-licensees of NERLYNX may choose or be forced to take similar action. Furthermore, the COVID-19 pandemic has resulted in dramatic increases in unemployment rates, which may result in a substantial number of people becoming uninsured or underinsured. Any of these developments may have an adverse effect on our revenue. The impact of the COVID-19 pandemic may also have a negative impact on our clinical trials of neratinib, as physicians may not be able to enroll clinical trials due to the previously mentioned restrictions.

Our ability to continue to operate without any significant negative impacts will in part depend on the length and severity of the COVID-19 pandemic and our ability to protect our employees and our supply chain. We continue to follow and monitor recommended actions of government and health authorities to protect our employees worldwide, but for the three months ended March 31, 2020, we and our key third-party suppliers and manufacturers were able to broadly maintain operations. We rely exclusively on third-party manufacturers to manufacture NERLYNX.

We intend to satisfy our near-term liquidity requirements through a combination of our existing cash and cash equivalents and marketable securities as of March 31, 2020 and proceeds that will become available to us through product sales, royalties and license milestone payments. However, this intention is based on assumptions that may prove to be wrong. Changes may occur that would consume our available capital faster than anticipated, including the length and severity of the COVID-19 pandemic and measures taken to control the spread of COVID-19, as well as changes in and progress of our development activities, the impact of commercialization efforts, acquisitions of additional drug candidates and changes in regulation.

For additional information, please refer to “Risk Factors” in Part II, Item 1A of this Quarterly Report.

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, 2020 from our accounting policies at December 31, 2019, as reported in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019. We had the following activity related to license agreements during the three months ended March 31, 2020:

License Revenue:

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

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

Pint Agreement:

During the first quarter of 2018, we entered into a license agreement, or the Pint Agreement, with Pint. The Pint Agreement granted intellectual property rights and set forth the respective obligations with respect to development, commercialization and supply of NERLYNX in Mexico and 21 countries and territories in Central and South America, or the Pint Territory. The Pint Agreement includes potential future milestone and royalty payments due to us upon successful completion of certain performance obligations, such as achieving regulatory approvals. Pursuant to the Pint Agreement, we received an upfront payment during the third quarter of 2018. The Pint Agreement also includes potential milestone and royalty payments due to us upon successful completion of certain performance obligations, such as achieving regulatory approvals, which would entitle us to receive payments totaling approximately $24.5 million if all respective performance obligations are achieved. During the third quarter of 2019 and the first quarter of 2020, we achieved two separate and distinct development-based milestones, which satisfied performance obligations necessary to recognize the associated license revenue. The payments associated with this license revenue are included in accounts receivable, net on the consolidated balance sheet as of March 31, 2020. In addition, we are entitled to receive double-digit royalties on sales of licensed products, calculated as a percentage of net sales of licensed products throughout the Pint Territory. At this time, we cannot estimate when these remaining milestone-related performance obligations might be achieved.

Summary of Income and Expenses

Product revenue, net:

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

License revenue:

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

Royalty revenue:

Royalty revenue consists of consideration earned related to product sales made by our licensees in their respective territories 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 sales also includes period costs related to royalty charges payable to Pfizer, the amortization of a milestone payment made to Pfizer after obtaining FDA approval of NERLYNX, certain inventory manufacturing services, inventory adjustment charges, unabsorbed manufacturing and overhead costs, and manufacturing variances.

Selling, general and administration expenses:

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

Research and development expenses:

R&D expenses include costs associated with services provided by consultants who conduct clinical services on our behalf, contract organizations for the manufacturing of clinical materials and clinical trials. During the three months ended March 31, 2020 and 2019, 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 R&D expenses primarily consist of payroll-related costs, but also include equipment costs, travel expenses and supplies.

Results of Operations

Three Months Ended March 31, 2020 Compared to Three Months Ended March 31, 2019

Total revenue:

For the three months ended March 31, 2020, total revenue was approximately $51.2 million, compared to $99.1 million for the three months ended March 31, 2019.

Product revenue, net:

Product revenue, net was approximately $48.6 million for the three months ended March 31, 2020, compared to $45.6 million for the three months ended March 31, 2019. The increase in product revenue, net was primarily attributable to an approximate 10% increase in gross selling price that occurred in the third quarter of 2019 and again in the first quarter of 2020, partially offset by a volume decrease of approximately 9% in bottles of NERLYNX.

License revenue:

License revenue was approximately $2.0 million for the three months ended March 31, 2020, compared to $53.5 million for the three months ended March 31, 2019. The decrease in license revenue is primarily due to us having upfront payments and satisfying different performance-based milestones related to sub-license agreements in the three months ended March 31, 2019, compared to the three months ended March 31, 2020.

Royalty revenue:

Royalty revenue was $0.6 million for the three months ended March 31, 2020, compared to no royalty revenue for the three months ended March 31, 2019. The increase was due to royalty revenue recognized related to the start of product sales by our sub-licensees.

Cost of sales:

For the three months ended March 31, 2020, cost of sales was approximately $9.1 million compared to $8.0 million for the three months ended March 31, 2019. The increase in cost of sales was primarily attributable to increased royalty expenses due to Pfizer, directly related to the increase in product revenue, net and royalty revenue.

Selling, general and administrative expenses:

For the three months ended March 31, 2020, SG&A expenses were approximately $30.9 million, compared to approximately $45.5 million for the three months ended March 31, 2019. SG&A expenses for the three months ended March 31, 2020 and 2019 were as follows:

Selling, general, and administrative expenses in thousands	**For the Three Months Ended March 31,**		**Change**	
			$	**%**
	2020	**2019**	**2020/2019**	**2020/2019**
Payroll and related costs	$ 10,567	$ 11,177	$ (610)	-5.5%
Professional fees and expenses	10,430	19,115	(8,685)	-45.4%
Travel and meetings	2,416	2,744	(328)	-12.0%
Facilities and equipment costs	1,437	1,439	(2)	-0.1%
Other	1,395	1,156	239	20.7%
Stock-based compensation	4,692	9,875	(5,183)	-52.5%
	$ 30,937	$ 45,506	$ (14,569)	-32.0%

For the three months ended March 31, 2020, SG&A expenses decreased by approximately $14.6 million compared to the same period in 2019, primarily attributable to the following:

- a decrease in professional fees and expenses of approximately $8.7 million, consisting of decreases of approximately $7.8 million in legal fees compared to the prior year period in connection with various lawsuits, approximately $0.9 million for delays of marketing events and programs due to the COVID-19 pandemic, and approximately $0.7 million for professional fees primarily related to decreased consultancy efforts related to marketing and commercialization support; partially offset by an increase of approximately $0.5 million in insurance premiums and audit fees and other immaterial fluctuations;
- a decrease in stock-based compensation expense of approximately $5.2 million primarily due to a decrease of approximately $3.8 million for stock awards that have fully vested and a decrease of approximately $2.6 million from stock awards forfeited; partially offset by an increase of approximately $1.2 million from new grants;
- a decrease of approximately $0.6 million in payroll and payroll-related expenses primarily due to reduction in headcount; and
- a decrease in travel and meetings of approximately $0.3 million related to commercialization efforts.

Research and development expenses:

For the three months ended March 31, 2020, R&D expenses were approximately $25.5 million, compared to approximately $35.7 million for the three months ended March 31, 2019. R&D expenses for the three months ended March 31, 2020 and 2019 were as follows:

Research and development expenses in thousands	**For the Three Months Ended March 31,**		**Change**	
			$	**%**
	2020	**2019**	**2020/2019**	**2020/2019**
Clinical trial expense	$ 8,811	$ 13,758	$ (4,947)	-36.0%
Internal R&D	10,229	10,144	85	0.8%
Consultant and contractors	2,200	3,563	(1,363)	-38.3%
Stock-based compensation	4,215	8,263	(4,048)	-49.0%
	$ 25,455	$ 35,728	$ (10,273)	-28.8%

For the three months ended March 31, 2020, R&D expenses decreased approximately $10.3 million compared to the same period in 2019, primarily attributable to the following:

- a decrease in clinical trial expense of approximately $4.9 million, primarily due to the close out of certain clinical trials;
- a decrease in employee stock-based compensation expense of approximately $4.0 million primarily due to a decrease of approximately $2.4 million for stock awards that fully vested, a decrease of approximately $1.6 million from stock award forfeitures and a decrease of $0.7 from a change in the estimated forfeiture rate; partially offset by an increase of approximately $0.7 million from new grants and other immaterial fluctuations; and
- a decrease in consultant and contractors expenses of approximately $1.4 million, primarily due to the close out of certain clinical trials.

Other income (expenses):

Other income (expenses) in thousands	**For the Three Months Ended March 31,**		**Change**	
			$	**%**
	2020	**2019**	**2020/2019**	**2020/2019**
Interest income	$ 386	$ 872	$ (486)	-55.7%
Interest expense	(3,068)	(4,443)	1,375	-30.9%
Legal verdict expense	(93)	(16,350)	16,257	-99.4%
Other income (expenses)	93	(14)	107	-764.3%
	$ (2,682)	$ (19,935)	$ 17,253	-86.5%

Interest income:

For the three months ended March 31, 2020, we recognized approximately $0.4 million in interest income compared to approximately $0.9 million of interest income for the three months ended March 31, 2019.

Interest expense:

For the three months ended March 31, 2020, we recognized approximately $3.1 million in interest expense, compared to $4.4 million of interest expense for the three months ended March 31, 2019. The decrease in interest expense was primarily the result of having less borrowings outstanding in the first quarter of 2020.

Legal verdict expense:

For the quarter ended March 31, 2020, we recognized $0.1 million in legal verdict expense that represents an estimate of service fees incurred related to the class action administrator as a result of the Hsu v. Puma Biotechnology, Inc., et al. claims process. For the quarter ended March 31, 2019, we recognized approximately $16.4 million in legal verdict expense related to the Eshelman v. Puma Biotechnology, Inc., et al. verdict. The legal verdict of $16.4 million is the result of our estimate of total damages payable in the matter of $22.4 million, net of $6.0 million in insurance reimbursements.

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of March 31, 2020 and December 31, 2019, and for the three months ended March 31, 2020 and 2019, and is intended to supplement the more detailed discussion that follows:

Liquidity and capital resources (in thousands)	March 31, 2020	December 31, 2019
Cash and cash equivalents	$ 83,385	$ 60,037
Marketable securities	$ 17,170	$ 51,607
Working capital	$ 68,214	$ 75,459
Stockholders' equity	$ 9,377	$ 17,463

	Three Months Ended March 31, 2020	Three Months Ended March 31, 2019
Cash provided by (used in):		
Operating activities	$ (11,540)	$ (16,130)
Investing activities	34,377	(44,583)
Financing activities	—	1,082
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 22,837	$ (59,631)

Operating Activities:

For the three months ended March 31, 2020 we reported a net loss of approximately $16.9 million, compared to approximately $10.1 million for the same period in 2019. Additionally, cash used in operating activities for the three months ended March 31, 2020 was approximately $11.5 million compared to approximately $16.1 million of cash used in operating activities for the same periods in 2019, respectively.

Cash used in operating activities for the three months ended March 31, 2020 consisted of a net loss of approximately $16.9 million, an increase in accounts receivable, net of approximately $2.6 million, an increase in prepaid expenses and other of approximately $1.1 million and a decrease in accounts payable of approximately $1.9 million; partially offset by approximately $10.8 million of non-cash items, such as stock-based compensation and depreciation and amortization and an increase in accrued expenses of approximately $0.4 million.

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

Investing Activities:

During the three months ended March 31, 2020, net cash provided by investing activities was approximately $34.4 million, compared to net cash used in investing activities of $44.6 million for the same period in 2019. Net cash provided by investing activities during the three months ended March 31, 2020 consisted of approximately $34.4 million of maturities of available-for-sale securities. Net cash used in investing activities during the three months ended March 31, 2019 consisted of approximately $86.7 million of cash invested in available-for-sale securities, offset by $42.1 million of maturities of available-for-sale securities.

Financing Activities:

During the three months ended March 31, 2020, there was no cash used in or provided by financing activities. During the same period in 2019, cash provided by financing activities was approximately $1.1 million, which consisted of approximately $1.1 million in net proceeds from the exercise of stock options.

Loan and Security Agreement:

In October 2017, we entered into a loan and security agreement with Silicon Valley Bank, or SVB, as administrative agent, and the lenders party thereto from time to time, or the Original Lenders, including Oxford Finance, LLC, or Oxford, and SVB. Pursuant to the terms of the credit facility provided for by the loan and security agreement, or the Original Credit Facility, we borrowed $50 million. In May 2018, we entered into an amendment to the loan and security agreement, which provided for an amended credit facility, or the Amended Credit Facility. Under the Amended Credit Facility, the Original Lenders agreed to make term loans available to us in an aggregate amount of $155 million, consisting of (i) a term loan in an aggregate amount of $125 million, the proceeds of which, in part, were used to repay the $50 million we borrowed under the Original Credit Facility, and (ii) a term loan in an aggregate amount of $30 million that we drew in December 2018, which was available to us under the Amended Credit Facility as a result of achieving a specified minimum revenue milestone. We were in compliance with all applicable financial covenants during the entire term of the Amended Credit Facility.

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

The New Credit Facility is secured by substantially all of our personal property other than our intellectual property. We also pledged 65% of the issued and outstanding capital stock of our subsidiaries, Puma Biotechnology Ltd. and Puma Biotechnology B.V. The New 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 New Credit Facility bear interest at an annual rate equal to the greater of (i) 9.0% and (ii) the sum of (a) the "prime rate," as reported in The Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 3.5%. We are required to make monthly interest-only payments on each term loan under the New Credit Facility commencing on the first calendar day of the calendar month following the funding date of such term loan, and continuing on the first calendar day of each calendar month thereafter through August 1, 2021, or the Amortization Date. Commencing on the Amortization Date, and continuing on the first calendar day of each calendar month thereafter, we will make consecutive equal monthly payments of principal, together with applicable interest, in arrears to each lender under the New Credit Facility, calculated pursuant to the New Credit Facility. All unpaid principal and accrued and unpaid interest with respect to each term loan under the New Credit Facility is due and payable in full on June 1, 2024, or the Maturity Date. Upon repayment of such term loans, we are also required to make a final payment to the new lenders equal to 7.5% of the aggregate principal amount of such term loans outstanding as of the Effective Date.

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

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

The New 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 Oxford, as collateral agent, with the right to exercise remedies against us and the collateral securing the New Credit Facility, including foreclosure against the property securing the New Credit Facility, including our cash. These events of default include, among other things, our failure to pay principal or interest due under the New Credit Facility, a breach of certain covenants under the New Credit Facility, our insolvency, a material adverse change, the occurrence of any default under certain other indebtedness in an amount greater than $500,000 and one or more judgments against us in an amount greater than $500,000 individually or in the aggregate that remains unsatisfied, unvacated, or unstayed for a period of 10 days after its entry.

As of March 31, 2020, there were $100.0 million in term loans outstanding under the New Credit Facility, representing all of our long-term debt outstanding as of that date, and we were in compliance with all applicable covenants under the New Credit Facility.

Current and Future Financing Needs:

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

We may choose to begin new R&D efforts or we may choose to launch additional marketing efforts. These efforts may require funding in addition to the cash and cash equivalents totaling approximately $83.4 million and $17.2 million in marketable securities available at March 31, 2020. While our consolidated financial statements have been prepared on a going concern basis, we expect to continue incurring significant losses for the foreseeable future and will need to generate significant revenue to sustain operations and successfully commercialize neratinib. While we have been successful in raising financing in the past, there can be no assurance that we will be able to do so in the future. Our ability to obtain funding may be adversely impacted by uncertain market conditions, including on account of the global COVID-19 pandemic, our success in commercializing neratinib, unfavorable decisions of regulatory authorities or adverse clinical trial results. The outcome of these matters cannot be predicted at this time. We believe that our existing cash and cash equivalents and marketable securities as of March 31, 2020 and proceeds that will become available to us through product sales and license payments are sufficient to satisfy our operating cash and needs for at least one year after the filing of this Quarterly Report.

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

Non-GAAP Financial Measures

In addition to our operating results, as calculated in accordance with generally accepted accounting principles, or GAAP, we use certain non-GAAP financial measures when planning, monitoring, and evaluating our operational performance. The following table presents our net loss and net loss per share, as calculated in accordance with GAAP, as adjusted to remove the impact of stock-based compensation. For the three months ended March 31, 2020 and 2019, stock-based compensation represented approximately 15.8% and 22.4% of our operating expenses, respectively, in each case excluding cost of sales. Our management believes that these non-GAAP financial measures are useful to enhance understanding of our financial performance, are more indicative of our operational performance and facilitate a better comparison among fiscal periods. These non-GAAP financial measures are not, and should not be viewed as, substitutes for GAAP reporting measures.

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

	For the Three Months Ended March 31,			
	2020		2019	
GAAP net loss	$ (16,933)		$ (10,087)	
Adjustments:				
Stock-based compensation -				
Selling, general and administrative	4,692		9,875	(1)
Research and development	4,215		8,263	(2)
Non-GAAP adjusted net (loss) income	$ (8,026)		$ 8,051	
GAAP net loss per share—basic	$ (0.43)		$ (0.26)	
Adjustment to net loss (as detailed above)	0.23		0.47	
Non-GAAP adjusted basic net (loss) income per share	$ (0.20)		$ 0.21	(3)
GAAP net loss per share—diluted	$ (0.43)		$ (0.26)	
Adjustment to net loss (as detailed above)	0.23		0.46	
Non-GAAP adjusted diluted net (loss) income per share	$ (0.20)	(4)	$ 0.20	(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) income per share was calculated based on 39,291,162 and 38,481,824 weighted-average shares of common stock outstanding for the three months ended March 31, 2020 and 2019, respectively.
(4) 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, 2020 as these shares would be considered anti-dilutive.
(5) Non-GAAP adjusted diluted net income per share was calculated based on 39,281,714 weighted-average shares of common stock outstanding for the three months ended March 31, 2019.

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, 2020. 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. As of March 31, 2020, the outstanding principal amount of our borrowings was $100.0 million. Our borrowings under the loan and security agreement, as amended, bear interest at an annual rate equal to the greater of (i) 9.0% and (ii) the sum of (a) the "prime rate," as reported in The Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 3.5%. Changes in the prime rate may therefore affect our interest expense associated with our borrowings under the loan and security agreement.

Item 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we have evaluated the effectiveness of our disclosure controls and procedures (as defined under Exchange Act Rule 13a-15(e)), as of March 31, 2020. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that these disclosure controls and procedures were effective as of March 31, 2020.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the three months ended March 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

Hsu v. Puma Biotechnology, Inc.

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

On September 9, 2019, the Court entered an order specifying the rate of prejudgment interest to be awarded on any valid claims at the 52-week Treasury Bill rate. The Court's order also established a claims process, which is expected to take about twelve months. A final judgment has not been entered.

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

In February 2016, Fredric N. Eshelman filed a lawsuit against our Chief Executive Officer and President, Alan H. Auerbach, and us in the United States District Court for the Eastern District of North Carolina (Case No. 7:16-cv-00018-D). The complaint generally alleged that we and Mr. Auerbach made defamatory statements regarding Dr. Eshelman in connection with a proxy contest. In May 2016, Dr. Eshelman filed a notice of voluntary dismissal of the claims against Mr. Auerbach. A trial on the remaining defamation claims against us took place from March 11 to March 15, 2019. At trial, the jury found us liable and awarded Dr. Eshelman $15.9 million in compensatory damages and $6.5 million in punitive damages. We strongly disagree with the verdict and, on April 22, 2019, filed a motion for a new trial or, in the alternative, a reduced damages award. The Court denied that motion on March 2, 2020. We have appealed that ruling and the verdict. Additionally, after trial, the plaintiff filed a motion seeking approximately $3 million in attorneys' fees, as well as pre-judgment interest. In the Court's March 2 ruling, it denied the motion for attorneys' fees but granted the request for pre-judgment interest, bringing the total judgment to $26.3 million. On March 30, 2020, the plaintiff filed a notice of cross-appeal and conditional cross-appeal, appealing the Court's order denying the plaintiff's request for attorneys' fees and conditionally cross-appealing a Court ruling that certain communications between Mr. Auerbach and his attorneys were protected by attorney-client privilege and a related evidentiary ruling. We estimate the high end of potential damages in the matter could be approximately $27.2 million; however, the actual amount of damages payable by us is still uncertain and will be ascertained only after completion of the appeal and any subsequent proceeding, and such amount could be greater than the amount of expense already recognized or the high end of the estimate.

Item 1A. RISK FACTORS

Under Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2019, which was filed with the SEC on February 28, 2020, we identified important factors that could affect our financial performance and could cause our actual results for future periods to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statements made in this Quarterly Report. There has been no material change in our risk factors subsequent to the filing of our Annual Report, except for the additional factor described below. However, the risks described in our Annual Report and below 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.

Our business, financial condition, results of operations and ongoing clinical trials could be harmed by the effects of the COVID-19 pandemic.

We are subject to various risks related to the global pandemic associated with COVID-19. For example, many geographic regions have imposed, or in the future may impose, "shelter-in-place" orders, quarantines or similar orders or restrictions to control the spread of COVID-19. These types of restrictions may deter or prevent cancer patients from traveling to see their doctors and result in a decline in revenue for NERLYNX, our only commercial product. Additionally, our commercial team and sales force have suspended travel and personal interactions with physicians and customers, including visits to healthcare provider officers, and are currently limited to conducting promotional activities virtually. The respective commercial teams of certain of the companies to which we sub-license the commercial rights of NERLYNX, and on which we rely for our international sales, have chosen or have been forced to take similar action, and other sub-licensees of NERLYNX may choose or be forced to take similar action. Furthermore, the pandemic has resulted in dramatic increases in unemployment rates, which may result in a substantial number of people becoming uninsured or underinsured. Any of these developments may have an adverse effect on our revenue and thus our ability to satisfy the minimum revenue covenants in our loan and security agreement.

Moreover, these types of restrictions could result in most of our other employees working from home, and could result in the employees of our key third-party vendors and manufacturers working from home. We rely exclusively on third-party manufacturers to manufacture NERLYNX. Neither we, nor our suppliers or manufacturers have significant experience operating with the majority of our respective work forces working from home, and this may disrupt standard operations for us or them, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our respective abilities to conduct business in the ordinary course. In addition, this may increase our cybersecurity risk, create data accessibility concerns and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, ethics committees, manufacturing sites, research or clinical trial sites and other important agencies and contractors. Our business interruption insurance, if available at all, may be insufficient to cover losses resulting from extended business interruptions from the COVID-19 pandemic.

Additionally, timely enrollment in our clinical trials is dependent upon global clinical trial sites, which may be adversely affected by the COVID-19 pandemic. We are currently conducting clinical trials for our product candidates in many countries, including the United States, the United Kingdom, Spain, Italy, France, South Korea, Australia, and Israel, and may expand to other geographies. Many of these regions are currently being or may in the future be affected by the COVID-19 pandemic. We have observed disruptions in patient enrollments in the United States and our SUMMIT basket trial. If the COVID-19 pandemic continues to spread in the geographies in which we are conducting clinical trials, we may experience additional disruptions in those clinical trials, which could have a material adverse impact on our clinical trial plans and timelines, including:

- delays in receiving authorizations from local regulatory authorities and ethics committees to initiate planned clinical trials;
- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruptions in global shipping that may affect the transport of clinical trial materials;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- delays in necessary interactions with local regulators, ethics committees and other third parties and contractors due to limitations in employee resources or forced furlough of government employees;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- refusal of the FDA to accept data from clinical trials in affected geographies.

Health regulatory agencies globally may also experience disruptions in their operations as a result of the COVID-19 pandemic. The FDA and comparable foreign regulatory agencies may have slower response times or be under-resourced to continue to monitor our clinical trials and, as a result, review, inspection and other timelines may be materially delayed. For example, in March 2020, the FDA announced its intention to temporarily postpone certain inspections of both foreign and domestic manufacturing facilities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. It is unknown how long such delays or disruptions could last. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates and commercialization efforts.

The continued spread of COVID-19 has also led to extreme disruption and volatility in the global capital markets, which increases the cost of, and adversely impacts access to, capital and increases economic uncertainty. While we expect COVID-19 to have an adverse impact on our business, given the rapid and evolving nature of the virus and the uncertainty about its impact on society and the global economy, we cannot predict the extent to which it will affect our global operations, particularly if these impacts persist or worsen over an extended period of time. To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also affect our ability to comply with certain covenants in our loan and security agreement or other agreements that are material to our business.

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, 2020.

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, 2020.

Item 3. DEFAULTS UPON SENIOR SECURITIES

None.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Item 5. OTHER INFORMATION

None.

Item 6. EXHIBITS

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

Exhibit Number	Description
3.1	Second Amended and Restated Certificate of Incorporation of the Company, as filed with the Secretary of State of the State of Delaware on June 14, 2016 (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on June 15, 2016 and incorporated herein by reference)
3.2	Third Amended and Restated Bylaws of the Company (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on May 28, 2019 and incorporated herein by reference)
10.1#**	First Amendment to Puma Biotechnology, Inc. 2011 Incentive Award Plan (filed as Appendix A to the Company's Proxy Statement on Form DEFR14A filed with the SEC on June 4, 2014 and incorporated herein by reference)
10.2*	First Amendment to Amended and Restated Loan and Security Agreement, dated February 27, 2020, by and between the Company and Oxford Finance LLC, as collateral agent and Lender (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on March 4, 2020 and incorporated herein by reference)
10.3+	Amended Non-Employee Director Compensation Program
31.1+	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, with respect to the registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020
31.2+	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, with respect to the registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020
32.1++	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2++	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS+	Inline XBRL Instance Document
101.SCH+	Inline XBRL Taxonomy Extension Schema Document
101.CAL+	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF+	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB+	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE+	Inline XBRL Taxonomy Extension Linkbase Document
104+	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)
+	Filed herewith
++	Furnished herewith
*	Portions of this exhibit (indicated by asterisks) have been omitted pursuant to Regulation S-K, Item 601(b)(10). Such omitted information is not material and would likely cause competitive harm to the registrant if publicly disclosed. Additionally, certain schedules and attachments to certain of these exhibits have been omitted pursuant to Regulation S-K, Item 601(a)(5).

** This exhibit has been included herein to properly incorporate it by reference. Due to an administrative error, an earlier version of the First Amendment to Puma Biotechnology, Inc. 2011 Incentive Award Plan, before it was subsequently revised (which revised version is properly incorporated herein by reference), was listed as Exhibit 10.2(b) in the Company's Annual Report on Form 10-K filed with the SEC on February 28, 2020.

Management contract or compensatory plan or arrangement.

SIGNATURES

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

PUMA BIOTECHNOLOGY, INC.

Date: May 7, 2020

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

Date: May 7, 2020

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

PUMA BIOTECHNOLOGY, INC.
NON-EMPLOYEE DIRECTOR COMPENSATION PROGRAM

(EFFECTIVE JANUARY 1, 2020)

Non-employee members of the board of directors (the "Board") of Puma Biotechnology, Inc. (the "Company") shall be eligible to receive cash and equity compensation as set forth in this Non-Employee Director Compensation Program (this "Program"). The cash and equity compensation described in this Program shall be paid or be made, as applicable, automatically and without further action of the Board, to each member of the Board who is not an employee of the Company or any subsidiary of the Company (each, a "Non-Employee Director") who may be eligible to receive such cash or equity compensation. This Program shall become effective as of the date set forth above.

Cash Compensation

Board Service	
Annual Retainer:	$50,000
Committee Service	
Audit Committee:	
Chair Annual Retainer:	$20,000
Committee Member (Non-Chair) Retainer:	$10,000
Compensation Committee:	
Chair Annual Retainer:	$15,000
Committee Member (Non-Chair) Retainer:	$7,500
Nominating and Corporate Governance Committee:	
Chair Annual Retainer:	$10,000
Committee Member (Non-Chair) Retainer:	$5,000
Research and Development Committee; Commercial Committee:	
Chair Annual Retainer:	$15,000

Committee Member (Non-Chair) Retainer:	$7,500

Board Service and Committee Service Annual Retainers will be paid or granted (as applicable) quarterly at the beginning of the applicable calendar quarter. In the event that a Non-Employee Director is initially elected or appointed to serve on the Board (the date of any such initial election or appointment, such Non-Employee Director's "Start Date") on any date other than the first day of a calendar quarter, such Non-Employee Director shall receive, within 30 days following such Non-Employee Director's Start Date, a prorated portion of the Board Service Annual Retainer and a prorated portion of each applicable Committee Service Annual Retainer, payable to such Non-Employee Director with respect to such quarter.

Equity Compensation

Non-Employee Directors shall be granted the equity awards described below. The awards described below shall be granted under and shall be subject to the terms and provisions of the Company's 2011 Incentive Award Plan, as may be amended from time to time (the "Plan"). Capitalized terms not otherwise defined below shall have the meanings ascribed to them in the Plan.

Initial Option Grant:	Each Non-Employee Director who is initially elected or appointed to serve on the Board is hereby granted an Option with a value of $700,000 (the "Initial Grant"). The number of Shares subject to the Initial Grant will be determined by dividing the value by the Black-Scholes valuation as of the grant date using a trailing 30-calendar day average closing price for the Company's common stock through and including the applicable grant date. The Initial Grant is hereby granted on the date on which such Non-Employee Director is initially elected or appointed to serve on the Board (the "Election Date"), and shall vest with respect to one-third (1/3rd) of the Shares subject thereto on the first anniversary of the applicable Election Date, and with respect to an additional 1/36th of the Shares subject thereto on each monthly anniversary thereafter, subject to continued service through the applicable vesting date. Each Initial Grant shall have an exercise price per Share equal to the Fair Market Value of a Share on the applicable Election Date.

Annual RSU Grant:	Each Non-Employee Director who is serving on the Board as of the date of any annual shareholder meeting on or after the effective date of this Program and will continue to serve as a Non-Employee Director immediately following such meeting, shall hereby be granted a Restricted Stock Unit award with a value of $300,000 (the "Annual Grant"). The number of Shares subject to the Annual Grant will be determined by dividing the value by the trailing 30-calendar day average closing price for the Company's common stock through and including the applicable grant date. Each Annual Grant will vest in full on the earlier of the one-year anniversary of the date of grant and the date of the annual shareholder meeting following the date of grant, subject to continued service.

Miscellaneous

Each Initial Grant shall be an Option and shall have a maximum term of ten years from the applicable date of grant. All applicable terms of the Plan apply to this Program as if fully set forth herein, and all grants of awards are hereby subject in all respect to the terms of the Plan. The grant of any award under this Program shall be made solely by and subject to the terms set forth in a written Award Agreement in a form approved by the Board and duly executed by an executive officer of the Company.

Non-Employee Director Award Limit

Notwithstanding any provision to the contrary in this Program, the sum of any cash compensation and the grant date fair value (determined as of the date of the grant under Financial Accounting Standards Board Accounting Standards Codification Topic 718, or any successor thereto) of all awards granted under this Program shall be subject to any limitations imposed under the Plan or any other applicable agreement, program, policy or plan.

Amendment, Modification and Termination

This Program may be amended, modified or terminated by the Board in the future at its sole discretion. No Non-Employee Director shall have any rights hereunder, except with respect to any awards actually granted pursuant to the Program.

Exhibit 31.1

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

I, Alan H. Auerbach, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended March 31, 2020;

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 7, 2020

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

Exhibit 31.2

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

I, Maximo F. Nougues, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended March 31, 2020;

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 7, 2020

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

Exhibit 32.1

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

The following certification is being furnished solely to accompany the Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended March 31, 2020, 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, 2020, 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 7, 2020

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

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

Exhibit 32.2

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

The following certification is being furnished solely to accompany the Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended March 31, 2020, pursuant to 18 U.S.C. § 1350 and in accordance with SEC Release No. 33-8238. This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference in any filing of Puma Biotechnology, Inc. under the Securities Act of 1933, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Certification of Principal Financial Officer

I, Maximo F. Nougues, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended March 31, 2020, 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 7, 2020

/s/ Maximo F. Nougues
Maximo F. Nougues
Principal Financial and Accounting Officer

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