UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2019

OR

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

For the transition period from _____ to_____

Commission File Number: 001-35703

PUMA BIOTECHNOLOGY, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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. 38,960,995 shares of Common Stock, par value $0.0001 per share, were outstanding as of November 1, 2019.

PUMA BIOTECHNOLOGY, INC.

- INDEX -

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

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

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

These statements are often, but not always, made through the use of words or phrases such as “anticipate,” “estimate,” “plan,” “project,” “continuing,” “ongoing,” “expect,” “believe,” “intend” and similar words or phrases. Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. Discussions containing these forward-looking statements may be found throughout this Quarterly Report on Form 10-Q, including, in Part I, the section entitled “Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.” These forward-looking statements involve risks and uncertainties, including the risks discussed in Part I, Item 1A. “Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2018 that could cause our actual results to differ materially from those in the forward-looking statements. Such risks should be considered in evaluating our prospects and future financial performance. We undertake no obligation to update the forward-looking statements or to reflect events or circumstances after the date of this document.

Part I – FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 58,904	$ 108,419
Marketable securities	51,535	57,002
Accounts receivable, net	27,182	20,773
Inventory, net	3,123	2,625
Prepaid expenses, current	9,990	12,397
Deferred rent	39	—
Other current assets	322	1,787
Total current assets	151,095	203,003
Lease right-of-use assets, net	20,194	—
Property and equipment, net	3,204	3,963
Intangible assets, net	41,447	44,408
Restricted cash	13,173	4,319
Prepaid expenses and other, long-term	2,931	3,429
Total assets	$ 232,044	$ 259,122
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 9,056	$ 20,684
Accrued expenses	76,771	46,431
Lease liabilities	2,516	—
Total current liabilities	88,343	67,115
Deferred rent	—	5,815
Lease liabilities, long-term	23,336	—
Post-marketing commitment liability	9,000	—
Long-term debt	94,185	151,886
Total liabilities	214,864	224,816
Stockholders' equity:		
Common stock - $.0001 par value per share; 100,000,000 shares authorized; 38,943,774 shares issued and outstanding at September 30, 2019 and 38,325,037 issued and outstanding at December 31, 2018	4	4
Additional paid-in capital	1,283,498	1,236,355
Receivable from exercise of stock options	—	—
Accumulated other comprehensive income (loss)	115	(12)
Accumulated deficit	(1,266,437)	(1,202,041)
Total stockholders' equity	17,180	34,306
Total liabilities and stockholders' equity	$ 232,044	$ 259,122

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue:				
Product revenue, net	$ 53,482	$ 52,629	$ 152,913	$ 139,412
License revenue	2,750	10,000	56,250	40,500
Royalty revenue	120	—	175	—
Total revenue	56,352	62,629	209,338	179,912
Operating costs and expenses:				
Cost of sales	9,371	9,048	26,673	24,262
Selling, general and administrative	31,402	28,502	110,435	105,239
Research and development	30,027	36,360	102,610	126,529
Total operating costs and expenses	70,800	73,910	239,718	256,030
Loss from operations	(14,448)	(11,281)	(30,380)	(76,118)
Other income (expenses):				
Interest income	569	590	2,349	1,093
Interest expense	(3,052)	(3,499)	(11,943)	(7,165)
Legal verdict expense	—	—	(16,350)	—
Loss on debt extinguishment	—	—	(8,103)	—
Other income (expenses):	46	(11)	31	(690)
Total other expenses:	(2,437)	(2,920)	(34,016)	(6,762)
Net loss	$ (16,885)	$ (14,201)	$ (64,396)	$ (82,880)
Net loss applicable to common stockholders	$ (16,885)	$ (14,201)	$ (64,396)	$ (82,880)
Net loss per share of common stock—basic and diluted	$ (0.44)	$ (0.37)	$ (1.67)	$ (2.19)
Weighted-average shares of common stock outstanding—basic and diluted	38,893,757	38,043,174	38,675,961	37,855,249

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 September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
Net loss	$ (16,885)	$ (14,201)	$ (64,396)	$ (82,880)
Other comprehensive loss				
Unrealized gain (loss) on available-for-sale securities	15	(2)	115	(3)
Reclassifications of (gain) loss on available-for-sale securities	(10)	—	12	—
Comprehensive loss	$ (16,880)	$ (14,203)	$ (64,269)	$ (82,883)

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 September 30, 2019

	Common Stock		Additional Paid-in Capital	Receivables from Exercises of Options	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Amount					
Balance at June 30, 2019	38,738,707	$ 4	$ 1,271,209	$ —	$ 110	$ (1,249,552)	$ 21,771
Stock-based compensation	—	—	12,213	—	—	—	12,213
Shares issued or restricted stock units vested under employee stock plans	205,067	—	76	—	—	—	76
Unrealized gain on available-for-sale securities	—	—	—	—	5	—	5
Net loss	—	—	—	—	—	(16,885)	(16,885)
Balance at September 30, 2019	38,943,774	$ 4	$ 1,283,498	$ —	$ 115	$ (1,266,437)	$ 17,180

For the Three Months Ended September 30, 2018

	Common Stock		Additional Paid-in Capital	Receivables from Exercises of Options	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Amount					
Balance at June 30, 2018	37,890,220	$ 4	$ 1,195,600	$ (159)	$ (1)	$ (1,157,145)	$ 38,299
Stock-based compensation	—	—	20,807	—	—	—	20,807
Shares issued or restricted stock units vested under employee stock plans	234,902	—	851	159	—	—	1,010
Unrealized loss on available-for-sale securities	—	—	—	—	(2)	—	(2)
Net loss	—	—	—	—	—	(14,201)	(14,201)
Balance at September 30, 2018	38,125,122	$ 4	$ 1,217,258	$ —	$ (3)	$ (1,171,346)	$ 45,913

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 Nine Months Ended September 30, 2019

	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, 2018	38,325,037	$ 4	$ 1,236,355	$ —	$ (12)	$ (1,202,041)	$ 34,306
Stock-based compensation	—	—	45,791	—	—	—	45,791
Shares issued or restricted stock units vested under employee stock plans	618,737	—	1,352	—	—	—	1,352
Unrealized gain on available-for-sale securities	—	—	—	—	127	—	127
Net loss	—	—	—	—	—	(64,396)	(64,396)
Balance at September 30, 2019	38,943,774	$ 4	$ 1,283,498	$ —	$ 115	$ (1,266,437)	$ 17,180

For the Nine Months Ended September 30, 2018

	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, 2017	37,594,851	$ 4	$ 1,142,213	$ (449)	$ —	$ (1,088,466)	$ 53,302
Stock-based compensation	—	—	68,343	—	—	—	68,343
Shares issued or restricted stock units vested under employee stock plans	530,271	—	6,702	449	—	—	7,151
Unrealized loss on available-for-sale securities	—	—	—	—	(3)	—	(3)
Net loss	—	—	—	—	—	(82,880)	(82,880)
Balance at September 30, 2018	38,125,122	$ 4	$ 1,217,258	$ —	$ (3)	$ (1,171,346)	$ 45,913

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

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

	For the Nine Months Ended September 30,	
	2019	2018
Operating activities:		
Net loss	$ (64,396)	$ (82,880)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	6,178	5,279
Stock-based compensation	45,791	68,343
Disposal of property and equipment	54	—
Loss on debt extinguishment	8,047	—
Debt modification fees	—	289
Changes in operating assets and liabilities:		
Accounts receivable, net	(6,409)	(10,080)
Inventory	(498)	(803)
Prepaid expenses and other	2,905	244
Other current assets	1,465	(11,495)
Accounts payable	(11,628)	(11,388)
Accrued expenses	30,340	10,869
Deferred rent	(39)	470
Post-marketing commitment liability	9,000	—
Net cash provided by (used in) operating activities	20,810	(31,152)
Investing activities:		
Purchase of property and equipment	—	(550)
Purchase of available-for-sale securities	(127,072)	(71,112)
Sale of available-for-sale securities	28,135	—
Maturity of available-for-sale securities	104,532	11,457
Net cash provided by (used in) investing activities	5,595	(60,205)
Financing activities:		
Net proceeds from shares issued under employee stock plans	1,352	7,151
Proceeds from long-term debt	25,000	75,000
Payment of debt	(80,000)	—
Payment of debt extinguishment costs	(7,793)	—
Payment of debt issuance costs	(5,625)	(4,192)
Net cash (used in) provided by financing activities	(67,066)	77,959
Net decrease in cash, cash equivalents and restricted cash	(40,661)	(13,398)
Cash, cash equivalents and restricted cash, beginning of period	112,738	86,015
Cash, cash equivalents and restricted cash, end of period	$ 72,077	$ 72,617
Supplemental disclosures of non-cash investing and financing activities:		
Property and equipment purchases in accounts payable	$ —	$ 59
Receivables related to stock option exercises	$ —	$ —
Supplemental disclosure of cash flow information:		
Interest paid	$ 9,464	$ 5,134

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 has in-licensed 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 U.S. commercialization of NERLYNX (neratinib), its first U.S. Food and Drug Administration, or FDA, approved product, and on the further development of the oral version of neratinib for additional indications in the treatment of HER2-positive breast cancer. The Company believes that neratinib has clinical application in the treatment of several other cancers as well, including 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 European Union.

Basis of Presentation:

The Company is focused on developing and commercializing neratinib for the treatment of patients with human epidermal growth factor receptor type 2, or HER2-positive, breast cancer, HER2 mutated breast cancer and non-small cell lung cancer, and other solid tumors that have an activating mutation in HER2. The Company has reported a net loss of approximately $16.9 million and $64.4 million for the three and nine months ended September 30, 2019, and cash flows from operations of approximately $20.8 million for the nine months ended September 30, 2019. 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.

The Company has incurred significant operating losses since its inception. On July 17, 2017, the Company received FDA approval for its first product, NERLYNX® (neratinib), formerly known as PB272 (neratinib (oral)), for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer following adjuvant trastuzumab-based therapy. Following FDA approval in July 2017, NERLYNX became available by prescription in the United States, and the Company commenced commercialization.

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

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

The Company’s commercialization, research and development, or R&D, or marketing efforts may require funding in addition to the cash and cash equivalents totaling approximately $58.9 million and marketable securities totaling approximately $51.5 million available at September 30, 2019. The Company believes that its existing cash and cash equivalents and marketable securities as of September 30, 2019 and proceeds that will become available to the Company through product sales and 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. 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, unfavorable decisions of regulatory authorities or adverse clinical trial results. The outcome of these matters cannot be predicted at this time.

Since its inception through September 30, 2019, the Company's financing has primarily been proceeds from product and license revenue, public offerings of its common stock, private equity placements, and borrowings under its loan and security agreement.

Note 2—Significant Accounting Policies:

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

Financial Instruments:

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

Use of Estimates:

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

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

Principles of Consolidation:

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

Investment Securities:

The Company classifies all investment securities (short-term and long-term) as available-for-sale, as the sale of such securities may be required prior to maturity to implement management's strategies. These securities are carried at fair value, with the unrealized gains and losses, reported as a component of accumulated other comprehensive loss in stockholders' equity until realized. Realized gains and losses from the sale of available-for-sale securities, if any, are determined on a specific identification basis. A decline in the market value of any available-for-sale security below cost that is determined to be other than temporary results in the revaluation of its carrying amount to fair value. The impairment is charged to earnings and a new cost basis for the security is established. Premiums and discounts are amortized or accreted over the life of the related security as an adjustment to yield using the straight-line method. Interest income is recognized when earned.

License Fees and Intangible Assets:

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

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

The Company assesses its intangible assets for impairment if indicators are present or changes in circumstance suggest that impairment may exist. Events that could result in an impairment, or trigger an interim impairment assessment, include the receipt of additional clinical or nonclinical data regarding one of the Company's drug candidates or a potentially competitive drug candidate, changes in the clinical development program for a drug candidate, or new information regarding potential sales of the drug. If impairment indicators are present or changes in circumstance suggest that impairment may exist, the Company performs a recoverability test by comparing the sum of the estimated undiscounted cash flows of each intangible asset to its carrying value on the consolidated balance sheet. If the undiscounted cash flows used in the recoverability test are less than the carrying value, the Company would determine the fair value of the intangible asset and recognize an impairment loss if the carrying value of the intangible asset exceeds its fair value. The FDA approval of NERLYNX in July 2017 triggered a one-time milestone payment pursuant to the Company's license agreement with the Pfizer. The Company capitalized the milestone payment as an intangible asset and is amortizing the asset to cost of sales on a straight-line basis through 2030, the estimated useful life of the licensed patent. The Company recorded amortization expense related to its intangible asset of $1.0 million and $3.0 million for the three and nine months ended September 30, 2019, respectively. As of September 30, 2019, estimated future amortization expense related to the Company's intangible asset was approximately $0.9 million for the remainder of 2019, approximately $3.9 million for each year starting 2020 through 2029, and approximately $1.0 million for 2030.

Royalties:

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

Leases:

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

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

The incremental borrowing rate presents the rate of interest that the Company would expect to pay on a collateralized basis to borrow an amount equal to the lease payments under similar terms. When determinable, the Company uses the rate implicit in the 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 incremental borrowing rate, or IBR, for existing leases on the transition date (January 1, 2019) was calculated as 10.9%.

Inventory:

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

The Company capitalizes inventory costs associated with the Company's products after regulatory approval, if any, when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. The Company previously expensed $4.5 million of product prior to receipt of marketing approval, which was recorded as R&D expense at the time it was incurred. Inventory that can be used in either the production of clinical or commercial product is recorded as R&D 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 costs in the consolidated statements of operations and comprehensive loss as incurred.

As of September 30, 2019, the Company's inventory balance consisted primarily of raw materials purchased subsequent to FDA approval of NERLYNX.

Revenue Recognition:

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

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

Product Revenue, Net:

The Company sells NERLYNX to a limited number of specialty pharmacies and specialty distributors in the United States. These customers subsequently resell the Company's products to patients and certain medical centers or hospitals. In addition to distribution agreements with these customers, the Company enters into arrangements with health care providers and payors that provide for government mandated and/or privately negotiated rebates, chargebacks and discounts with respect to the purchase of the Company's products.

The Company recognizes revenue on product sales when the specialty pharmacy or specialty distributor, as applicable, obtains control of the Company's product, which occurs at a point in time (upon delivery). Product revenue is recorded net of applicable 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 these customers relating to product sales and remitted to governmental authorities, they will be excluded from revenue. The Company expenses incremental costs of obtaining a contract when incurred, if the expected amortization period of the asset that the Company would have recognized is one year or less. However, no such costs were incurred during the three months ended September 30, 2019.

Product revenue from customers who individually accounted for 10% or more of the Company's total revenue for the three months ended September 30, 2019 consisted of the following, shown as a percentage of total revenue:

	Three Months Ended September 30, 2019
CVS/Caremark	36%
Accredo/Acaria	21%

License Revenue:

The Company also recognizes license revenue under certain of the Company's license agreements that are within the scope of ASC Topic 606. The terms of these agreements may contain multiple performance obligations, which may include licenses and research and development activities. The Company evaluates these agreements under ASC Topic 606 to determine the distinct performance obligations. Non-refundable, upfront fees that are not contingent on any future performance and require no consequential continuing involvement by the Company, are recognized as license 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 license 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. License revenue is recognized by measuring the progress toward complete satisfaction of the performance obligations using an input measure.

Knight Agreement

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

Pierre Fabre Agreement

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

Pint Agreement

During the first quarter of 2018, the Company 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. The Pint Agreement includes potential future milestone and royalty payments due to the Company upon successful completion of certain performance obligations, such as achieving regulatory approvals. Pursuant to the Pint Agreement, the Company received an upfront payment of $10.0 million during the third quarter of 2018 and will potentially receive additional regulatory and commercial milestone payments totaling up to approximately $24.5 million, as well as double-digit royalties on NERLYNX sales throughout the territory covered by the Pint Agreement. During the third quarter of 2019, the Company achieved a certain development-based milestone, which satisfied a performance obligation necessary to recognize the associated license revenue. The payment associated with this license revenue is expected to be received from Pint during the third quarter of 2020. At this time, the Company cannot estimate 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 licensees in their respective territories. The Company recognizes royalty revenue when the performance obligations have been satisfied.

Reserves for Variable Consideration:

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

The amount of variable consideration that is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. The Company's analyses also contemplated application of the constraint in accordance with the guidance, under which it determined a material reversal of revenue would not occur in a future period for the estimates detailed below as of September 30, 2019 and, therefore, the transaction price was not reduced further during the quarter ended September 30, 2019. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Trade Discounts and Allowances:

The Company generally provides customers with discounts, which include incentive fees that are explicitly stated in the Company's contracts and are recorded as a reduction of product revenue in the period the related product revenue is recognized. The reserve for discounts is established in the same period that the related product revenue is recognized, together with reductions to trade receivables, net on the consolidated balance sheets. In addition, the Company compensates its customers for sales order management, data, and distribution services. The Company has determined such services received to date are not distinct from the Company's sale of products to its customers and, therefore, these payments have been recorded as a reduction of product revenue within the statement of operations and comprehensive loss through September 30, 2019.

Product Returns:

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

Provider Chargebacks and Discounts:

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

Government Rebates:

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

Payor Rebates:

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

Other Incentives:

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

Assets Measured at Fair Value on a Recurring Basis:

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

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

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

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

Following are the major categories of assets measured at fair value on a recurring basis as of September 30, 2019 and December 31, 2018, using quoted prices in active markets for identical assets (Level 1), significant other observable inputs (Level 2), and significant unobservable inputs (Level 3) (in thousands):

September 30, 2019	Level 1	Level 2	Level 3	Total
Cash equivalents	$ 40,935	$ —	$ —	$ 40,935
Commercial paper	—	—	—	—
Corporate bonds	—	41,501	—	41,501
U.S. government securities	10,034	—	—	10,034
Totals	$ 50,969	$ 41,501	$ —	$ 92,470

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

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

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

September 30, 2019	Maturity (in years)	Amortized cost	Unrealized Gains	Unrealized Losses	Estimated fair value
Cash equivalents		$ 40,935	$ —	$ —	$ 40,935
Commercial paper	Less than 1	—	—	—	—
Corporate bonds	Less than 1	41,396	105	—	41,501
U.S. government securities	Less than 1	10,024	10	—	10,034
Totals		$ 92,355	$ 115	$ —	$ 92,470

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

Concentration of Risk:

Financial instruments, which potentially subject the Company to concentrations of credit risk, principally consist of cash and cash equivalents and accounts receivable. The Company's cash and cash equivalents and restricted cash in excess of the Federal Deposit Insurance Corporation and the Securities Investor Protection Corporation insured limits at September 30, 2019, were approximately $75.7 million. The Company does not believe it is exposed to any significant credit risk due to the nature of the financial instruments in which the money is held. Pursuant to the Company's internal investment policy, investments must be rated A-1/P-1 or better by Standard and Poor's Rating Service and Moody's Investors Service at the time of purchase.

The Company sells its products in the United States primarily through specialty pharmacies and specialty distributors. Therefore, wholesale distributors and large pharmacy chains account for a large portion of its trade receivables and net product revenue. The Company monitors the creditworthiness of its customers and has internal policies regarding customer credit limits. The Company estimates an allowance for doubtful accounts primarily based on the credit worthiness of its customers, historical payment patterns, aging of receivable balances and general economic conditions.

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

The Company relies exclusively on third parties to formulate and manufacture NERLYNX and its drug candidates. The commercialization of NERLYNX and any other drug candidates, if approved, could be stopped, delayed or made less profitable if those third parties fail to provide sufficient quantities of product or fail to do so at acceptable quality or price. 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 or its 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.

Research and Development Expenses:

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

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

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

Stock-Based Compensation:

Stock option awards:

ASC 718, *Compensation-Stock Compensation*, or ASC 718, requires the fair value of all share-based payments to employees, including grants of stock options, to be recognized in the statement of operations over the requisite service period. The fair value of each option award is estimated on the grant date using the Black-Scholes Option Pricing Method and those valuations do not change once they have been established. As allowed by ASC 718, the Company's estimate of expected volatility is based on its average volatilities using its past six years of publicly traded history. Beginning in 2018, the Company estimated its expected volatility based on its average volatilities using its past six years of publicly traded stock history. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant valuation. Option forfeitures are calculated when the option is granted to reduce the option expense to be recognized over the life of the award and updated upon receipt of further information as to the amount of options expected to be forfeited. The option expense is "trued-up" upon the actual forfeiture of a stock option grant. Due to its limited history of stock option exercises, the Company uses the simplified method to determine the expected life of the option grants.

Restricted stock units:

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

Income Taxes:

The Company follows ASC 740, Income Taxes, or ASC 740, which requires recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements or tax returns. Under this method, deferred tax assets and liabilities are based on the differences between the consolidated financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the temporary differences are expected to be recovered or settled. 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.

The standard addresses the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the consolidated financial statements. Under ASC 740, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the tax authorities, based on the technical merits of the position. The tax benefits recognized in the consolidated financial statements from such a position should be measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. ASC 740 also provides guidance on de-recognition, classification, interest and penalties on income taxes, accounting in interim periods and requires increased disclosures. As of September 30, 2019, the Company has established a reserve of 20% of its R&D credit carryover balance.

Segment Reporting:

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

Net Loss per Common Share:

Basic net loss per share of common stock is computed by dividing net loss applicable to common stockholders by the weighted average number of shares of common stock outstanding during the periods presented, as required by ASC 260, *Earnings per Share*. For purposes of calculating diluted loss per share of common stock, the denominator includes both the weighted average number of shares of common stock outstanding and the number of dilutive common stock equivalents, such as stock options, RSUs and warrants. A common stock equivalent is not included in the denominator when calculating diluted earnings per common share if the effect of such common stock equivalent would be anti-dilutive. For the three and nine months ended September 30, 2019, potentially dilutive securities excluded from the calculations were 5,076,766 shares issuable upon exercise of options, 2,116,250 shares issuable upon exercise of a warrant, and 1,635,242 shares underlying RSUs that were subject to vesting and were antidilutive. For the three and nine months ended September 30, 2018, potentially dilutive securities excluded from the calculations were 5,763,609 shares issuable upon exercise of options, 2,116,250 shares issuable upon exercise of a warrant, and 1,541,970 shares underlying RSUs that were subject to vesting and were antidilutive.

Recently Adopted Accounting Standards:

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

Note 3—Accounts Receivable, Net:

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

	September 30, 2019	December 31, 2018
Accounts receivable	$ 24,682	$ 20,773
License revenue receivable	2,500	—
Total accounts receivable, net	$ 27,182	$ 20,773

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.

Note 4—Prepaid Expenses and Other:

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

	September 30, 2019	December 31, 2018
Current:		
CRO services	$ 4,661	$ 5,824
Other clinical development	2,053	888
Insurance	407	2,446
Professional fees	597	272
Other	2,272	2,967
	9,990	12,397
Long-term:		
CRO services	1,657	1,073
Other clinical development	7	650
Other	1,267	1,706
	2,931	3,429
Totals	$ 12,921	$ 15,826

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

Note 5—Other Current Assets:

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

	September 30, 2019	December 31, 2018
Insurance receivable	$ —	$ 1,175
Other	322	612
Totals	$ 322	$ 1,787

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

Note 6—Leases:

Components of lease expense include fixed lease expense and variable lease expense of approximately $3.6 million and $0.3 million, respectively, for the nine months ended September 30, 2019. For purposes of determining straight-line rent expense, the lease term is calculated from the date the Company first takes possession of the facility, including any periods of free rent and any renewal option periods that the Company is reasonably certain of exercising. Our office and equipment leases generally have contractually specified minimum rent and annual rent increases are included in the measurement of the right-of-use asset and related lease liability. Additionally, under these lease arrangements, we may be required to pay directly, or reimburse the lessors, for real estate taxes, insurance, utilities, maintenance and other operating costs. Such amounts are generally variable and therefore not included in the measurement of the ROU asset and related lease liability but are instead recognized as variable lease expense in selling, general and administrative costs in the consolidated statements of operations and comprehensive loss when they are incurred. The Company recorded operating sublease income of $0.1 million for the three and nine months ended September 30, 2019 in other income in the consolidated statements of operations and comprehensive loss.

Supplemental cash flow information related to leases for the nine months ended September 30, 2019:

Operating cash flows from operating leases (in thousands)	$ 4,050
Right-of-use assets obtained in exchange for new operating lease liabilities	—
Weighted average remaining lease term (in years)	6.5
Weighted average discount rate	10.9%

The maturity of lease liabilities as of September 30, 2019 were as follows (in thousands):

	Amount
2019 (remaining)	$ 1,274
2020	5,207
2021	5,365
2022	5,483
2023	5,631
Thereafter	13,296
Total	**$ 36,256**
Less: imputed interest	(10,404)
Total lease liabilities	**$ 25,852**

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

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

Note 7—Property and Equipment:

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

	September 30, 2019	December 31, 2018
Leasehold improvements	$ 3,780	$ 4,048
Computer equipment	2,367	2,402
Telephone equipment	340	343
Furniture and fixtures	2,346	2,346
	8,833	9,139
Less: accumulated depreciation	(5,629)	(5,176)
Totals	$ 3,204	$ 3,963

For the three months and nine months ended September 30, 2019, the Company incurred depreciation expense of $0.2 million and $0.7 million, respectively.

Note 8—Intangible assets, net:

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

	September 30, 2019	Estimated Useful Life
Acquired and in-licensed rights	$ 50,000	13 Years
Less: accumulated amortization	(8,553)	
Total intangible asset, net	$ 41,447	

For the three months and nine months ended September 30, 2019, the Company incurred amortization expense of $1.0 million and $3.0 million, respectively.

Note 9—Accrued Expenses:

Accrued expenses consisted of the following (in thousands):

	September 30, 2019	December 31, 2018
Accrued legal verdict expense	$ 31,350	$ 9,000
Accrued CRO services	13,923	10,187
Accrued royalties	8,040	9,162
Accrued variable consideration	6,406	3,818
Accrued compensation	3,569	4,435
Accrued professional fees	1,061	2,175
Accrued other clinical development	3,425	2,380
Accrued bonus	5,119	1,705
Accrued legal fees	886	1,379
Accrued manufacturing costs	1,095	788
Other	1,897	1,402
Totals	$ 76,771	$ 46,431

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 $9.0 million and $18.0 million that may be owed to class action participants as a result of the recent jury verdict in *Hsu v. Puma Biotechnology, Inc.,* and an initial estimate of $22.4 million that may be owed to the plaintiff as a result of the recent jury verdict in *Eshelman v. Puma Biotechnology, Inc., et al.* The total amount of 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 10—Debt:

Long term debt consisted of the following at September 30, 2019 (dollars in thousands):

	September 30, 2019	Maturity Date
Long term debt	$ 100,000	June 1, 2024
Accretion of final interest payment	1,603	
Less: deferred financing costs	(7,418)	
Total long term debt, net	$ 94,185	

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 subsidiary and any subsidiaries the Company creates in the future. The affirmative covenants include, among others, covenants requiring the Company to maintain its legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and satisfy certain requirements regarding deposit accounts. 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, for the periods ending June 30, 2019, September 30, 2019 and December 31, 2019. New minimum revenue levels will be established for each subsequent fiscal year by mutual agreement of the Company, Oxford, as collateral agent, and the new lenders. The negative covenants include, among others, restrictions on the Company's transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, creating liens, selling assets and suffering a change in control, in each case subject to certain exceptions.

The 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 its 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 September 30, 2019, 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.

Note 11—Stockholders' Equity:

Common Stock:

The Company issued 87,625 and 187,754 shares of common stock upon exercise of stock options during the nine months ended September 30, 2019 and 2018, respectively. The Company issued 531,112 and 332,173 shares of common stock upon vesting of RSUs during the nine months ended September 30, 2019 and 2018, respectively.

Authorized Shares:

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

Warrants:

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

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

Stock Options and Restricted Stock Units:

The Company's 2011 Incentive Award Plan, as amended, or the 2011 Plan, was adopted by the Company's board of directors on September 15, 2011. Pursuant to the 2011 Plan, the Company may grant incentive stock options and nonqualified stock options, as well as other forms of equity-based compensation. Incentive stock options may be granted only to employees, while consultants, employees, officers and directors are eligible for the grant of nonqualified options under the 2011 Plan. The maximum term of stock options granted under the 2011 Plan is 10 years. The exercise price of incentive stock options granted under the 2011 Plan must be at least equal to the fair value of such shares on the date of grant. Through September 30, 2019, a total of 12,529,412 shares of the Company's common stock had been reserved for issuance under the 2011 Plan.

As of September 30, 2019, 6,146,363 shares of the Company's common stock are issuable upon the exercise of outstanding awards granted under the 2011 Plan and 2,801,058 shares of the Company's common stock are available for future issuance under the 2011 Plan. The fair value of options granted to employees was estimated using the Black-Scholes Option Pricing Method (see Note 2) with the following weighted-average assumptions used during the nine months ended September 30, 2019 and 2018:

	2019	2018
Dividend yield	0.0%	0.0%
Expected volatility	99.9%	95.5%
Risk-free interest rate	2.5%	2.5%
Expected life in years	5.76	5.85

The Company's 2017 Employment Inducement Incentive Award Plan, or the 2017 Plan, was adopted by the Company's Board of Directors on April 27, 2017. Pursuant to the 2017 Plan, the Company may grant stock options and RSUs, as well as other forms of equity-based compensation to employees, as an inducement to join the Company. The maximum term of stock options granted under the 2017 Plan is 10 years. The exercise price of stock options granted under the 2017 Plan must be at least equal to the fair market value of such shares on the date of grant. As of September 30, 2019, a total of 1,000,000 shares of the Company's common stock have been reserved for issuance under the 2017 Plan. As of September 30, 2019, 565,645 shares have been awarded under the 2017 Plan.

Stock-based compensation was as follows for the three and nine months ended September 30 (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
Stock-based compensation:				
Options -				
Selling, general, and administrative	$ 1,768	$ 3,132	$ 6,706	$ 11,721
Research and development	1,786	5,387	6,001	22,689
Restricted stock units -				
Selling, general, and administrative	3,832	6,280	16,221	15,228
Research and development	4,827	6,008	16,863	18,705
Total stock-based compensation expense	$ 12,213	$ 20,807	$ 45,791	$ 68,343

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

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2018	5,708,544	$ 87.49	6.1	$ 7,762
Granted	129,734	$ 27.76	9.4	
Forfeited	(69,969)	$ 40.50		
Exercised	(87,625)	$ 15.42		$ 995
Expired	(603,918)	$ 102.39		
Outstanding at September 30, 2019	5,076,766	$ 86.08	5.4	$ 2,450
Nonvested at September 30, 2019	396,948	$ 39.99	8.6	

At September 30, 2019, total estimated unrecognized employee compensation cost related to non-vested stock options granted prior to that date was approximately $10.0 million, which is expected to be recognized over a weighted-average period of 1.4 years. At September 30, 2019, the total estimated unrecognized employee compensation cost related to non-vested RSUs was approximately $48.8 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 nine months ended September 30, 2019 and 2018 was $21.82 and $56.46 per share, respectively. The weighted average grant date fair value of RSUs awarded during the nine months ended September 30, 2019 and 2018 was $20.36 and $62.11 per share, respectively.

Stock Option Rollforward

Stock options	Shares	Weighted Average Grant-Date Fair Value
Nonvested shares at December 31, 2018	779,292	$ 33.75
Granted	129,734	21.82
Vested/Issued	(442,109)	35.13
Forfeited	(69,969)	25.06
Nonvested shares at September 30, 2019	396,948	$ 29.85

Restricted Stock Unit Rollforward

Restricted stock units	Shares	Weighted Average Grant-Date Fair Value
Nonvested shares at December 31, 2018	1,838,670	$ 60.08
Granted	776,730	20.36
Vested/Issued	(531,112)	70.06
Forfeited	(449,046)	53.02
Nonvested shares at September 30, 2019	1,635,242	$ 39.91

Note 12—401(k) Savings Plan:

The Company maintains a 401(k) savings plan for the benefit of its employees. The Company is required to make matching contributions to the 401(k) plan equal to 100% of the first 3% of wages deferred by each participating employee and 50% on the next 2% of wages deferred by each participating employee. The Company incurred expenses for employer matching contributions of approximately $1.2 million and $1.3 million for the nine months ended September 30, 2019 and 2018, respectively.

Note 13—Commitments and Contingencies:

Contractual Obligations:

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

License Agreement:

In August 2011, the Company entered into an agreement pursuant to which Pfizer agreed to grant it a worldwide license for the development, manufacture and commercialization of PB272 neratinib (oral), PB272 neratinib (intravenous) and PB357, and certain related compounds. The license is exclusive with respect to certain patent rights owned by or licensed to Pfizer. Under the agreement, the Company is obligated to commence a new clinical trial for a product containing one of these compounds within a specified period of time and to use commercially reasonable efforts to complete clinical trials and to achieve certain milestones as provided in a development plan. From the closing date of the agreement through December 31, 2011, Pfizer continued to conduct the existing clinical trials on behalf of the Company at 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. 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 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 to January 29, 2019. At trial, the jury found that three of the four challenged statements were not false or misleading, and thus found in the defendants' favor on those claims. The jury found liability as to one statement and awarded a maximum of $4.50 per share in damages, which represents approximately 5% of the total claimed damages of $87.20 per share. The total amount of aggregate class-wide damages is uncertain and will be ascertained only after an extensive claims process and the exhaustion of any appeals. Trading models suggest that approximately ten million shares traded during the class period may be eligible to claim damages. Based on prior lawsuits, the Company believes that the number of stockholders who submit proof of claims sufficient to recover damages is typically in the range of 20% to 40% of the total eligible shares. Based on these assumptions, total damages after claims could range from $9 million to $18 million. It is also reasonably possible that the total damages will be higher than this estimate, however, at this time, the amount is not estimable.

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 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 plaintiff has since filed motions seeking attorneys' fees and pre-judgment interest, which if granted could increase the judgment amount. The Company strongly disagrees with the verdict and, on April 22, 2019, filed a motion for a new trial or, in the alternative, a reduced damages award. If the verdict is upheld, pending the outcome of that motion, the Company intends to appeal the verdict. The Company estimates the high end of potential damages in the matter could be approximately $26.3 million; however, the actual amount of damages payable by the Company is still uncertain and will be ascertained only after completion of post-trial proceedings and the exhaustion of any appeals, and such amount could be greater than the amount of expense already recognized or the high end of the estimate.

Note 14—Subsequent Events:

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

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and the notes thereto included in Item 1 in this Quarterly Report on Form 10-Q. The following discussion should also be read in conjunction with our audited consolidated financial statements and the notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K for the year ended December 31, 2018.

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

Overview

We are a biopharmaceutical company with a focus on the development and commercialization of innovative products to enhance cancer care. We have in-licensed 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 epidermal growth factor receptors, HER1, HER2 and HER4. Currently, we are primarily focused on the development and commercialization of the oral version of neratinib, and our most advanced drug candidates are directed at the treatment of HER2-positive breast cancer. We believe neratinib has clinical application in the treatment of several other cancers as well, including 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. During 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. We currently market NERLYNX in the United States using our direct specialty sales force consisting of approximately 80 sales specialists. Our sales specialists are supported by an experienced sales leadership team consisting of regional managers, and our commercial team of experienced professionals in marketing, access and reimbursement, managed markets, marketing research, commercial operations and sales force planning and management. In September 2018, the European Commission, or EC, granted marketing authorisation for NERLYNX in the European Union, and in the third quarter of 2019, our licensees, Knight Therapeutics, or Knight, and Pint Pharma International SA, or Pint, received marketing authorization for NERLYNX in Canada and Argentina, respectively.

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

Our expenses to date have been related to hiring staff, commencing company-sponsored clinical trials and the build out of our corporate infrastructure and, since 2017, the commercial launch of NERLYNX. 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.

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 and nine months ended September 30, 2019 from our accounting policies at December 31, 2018, as reported in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018. We had the following activity related to license agreements during the nine months ended September 30, 2019:

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.

Knight Agreement

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

Pierre Fabre Agreement

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

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. 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 of $10.0 million during the third quarter of 2018 and will potentially receive additional regulatory and commercial milestone payments totaling up to approximately $24.5 million, as well as double-digit royalties on NERLYNX sales throughout the territory covered by the Pint Agreement. During the third quarter of 2019, we achieved a certain development-based milestone, which satisfied a performance obligation necessary to recognize the associated license revenue. The payment associated with this license revenue is expected to be received from Pint during the third quarter of 2020. 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 related personnel costs, including stock-based compensation expense, professional fees, business insurance, rent, general legal activities, and other corporate expenses. Internal expenses primarily consist of payroll-related costs, but also include facilities and equipment costs, travel expenses and supplies. External expenses primarily consist of legal fees, insurance expenses and consulting for activities such as sales, marketing and software implementations to support corporate growth.

We expect overall SG&A expenses in 2019 to be similar to those in 2018. Additionally, we are currently appealing the verdicts in two trials and may incur substantial legal expenses in connection with these appeals. However, we are currently unable to estimate the magnitude of such legal expenses and when these expenses will cease.

Research and development expenses:

R&D expenses include costs associated with services provided by consultants who conduct clinical services on our behalf, contract organizations for the manufacturing of clinical materials and clinical trials. During the three and nine months ended September 30, 2019 and 2018, our R&D expenses consisted primarily of clinical research organization, or CRO, fees; fees paid to consultants; salaries and related personnel costs; and stock-based compensation. We expense our R&D costs as they are incurred. Internal R&D expenses primarily consist of payroll-related costs, but also include equipment costs, travel expenses and supplies. External expenses primarily consist of clinical trial expenses and consultant and contractor expense, and also include costs such as legal fees, insurance costs and manufacturing expense.

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

Results of Operations

Three Months Ended September 30, 2019 Compared to Three Months Ended September 30, 2018

Total revenue:

For the three months ended September 30, 2019, total revenue was approximately $56.4 million, compared to $62.6 million for the three months ended September 30, 2018.

Product revenue, net:

Product revenue, net was approximately $53.5 million for the three months ended September 30, 2019, compared to $52.6 million for the three months ended September 30, 2018. The increase in product revenue, net was primarily attributable to a 10% increase in gross selling price that occurred in the first quarter of 2019 and again in the third quarter of 2019, partially offset by an increase in variable consideration of approximately 12% in the third quarter of 2019 as compared to approximately 7% in the third quarter of 2018.

License revenue:

License revenue was approximately $2.8 million for the three months ended September 30, 2019, compared to $10.0 million for the three months ended September 30, 2018. The decrease in license revenue related to our having achieved performance-based milestones under two different license agreements in the three months ended September 30, 2019, compared to an upfront payment for the satisfaction of a performance obligation under another license agreement during the three months ended September 30, 2018.

Royalty revenue:

Royalty revenue was $0.1 million for the three months ended September 30, 2019, compared to no royalty revenue for the three months ended September 30, 2018. The increase was due to royalty revenue recognized related to product sales by our licensees as they begin to sell in their respective territories.

Cost of sales:

For the three months ended September 30, 2019, cost of sales was approximately $9.4 million compared to $9.0 million for the three months ended September 30, 2018. The increase in cost of sales was primarily attributable to increased royalty expenses due to Pfizer, directly related to the increase in product revenue.

Selling, general and administrative expenses:

For the three months ended September 30, 2019, SG&A expenses were approximately $31.4 million, compared to approximately $28.5 million for the three months ended September 30, 2018. SG&A expenses for the three months ended September 30, 2019 and 2018 were as follows:

Selling, general, and administrative expenses in thousands	For the Three Months Ended September 30,		Change	
			$	%
	2019	2018	2019/2018	2019/2018
Payroll and related costs	$ 9,586	$ 10,918	$ (1,332)	-12.2%
Professional fees and expenses	10,526	3,037	7,489	246.6%
Travel and meetings	2,964	2,428	536	22.1%
Facilities and equipment costs	1,439	1,558	(119)	-7.6%
Other	1,287	1,150	137	11.9%
Stock-based compensation	5,600	9,411	(3,811)	-40.5%
	$ 31,402	$ 28,502	$ 2,900	10.2%

For the three months ended September 30, 2019, SG&A expenses increased by approximately $2.9 million compared to the same period in 2018, primarily attributable to the following:

- an increase in professional fees and expenses of approximately $7.5 million, consisting of an increase of approximately $6.7 million in legal fees due to insurance reimbursements recorded in the prior period for legal fees in connection with various lawsuits, an increase of approximately $0.5 million for consulting fees primarily related to marketing and commercialization support, and an increase of approximately $0.3 million in insurance premiums;
- an increase in travel and meetings of approximately $0.5 million related primarily to commercialization efforts; and
- an increase in other expenses of approximately $0.1 million related to a companion drug co-pay assistance program;

which were partially offset by:

- a decrease in employee stock-based compensation expense of approximately $3.8 million, due primarily to a decrease of approximately $2.5 million from employee turnover, and a decrease of approximately $2.6 million for stock options and RSUs that have fully vested, partially offset by an increase of approximately $1.3 million from new grants;
- a decrease of approximately $1.3 million in payroll and payroll-related expenses primarily due to a reduction in sales commissions; and
- a decrease in facilities and equipment costs of approximately $0.1 million.

Research and development expenses:

For the three months ended September 30, 2019, R&D expenses were approximately $30.0 million, compared to approximately $36.4 million for the three months ended September 30, 2018. R&D expenses for the three months ended September 30, 2019 and 2018 were as follows:

Research and development expenses in thousands	**For the Three Months Ended September 30,**		**Change**	
			$	**%**
	2019	**2018**	**2019/2018**	**2019/2018**
Clinical trial expense	$ 11,251	$ 12,222	$ (971)	-7.9%
Internal R&D	9,512	10,441	(929)	-8.9%
Consultant and contractors	2,651	2,302	349	15.2%
Stock-based compensation	6,613	11,395	(4,782)	-42.0%
	$ 30,027	$ 36,360	$ (6,333)	-17.4%

For the three months ended September 30, 2019, R&D expenses decreased approximately $6.3 million compared to the same period in 2018, primarily attributable to the following:

- a decrease in employee stock-based compensation expense of approximately $4.8 million, due primarily to a decrease of approximately $3.3 million from employee turnover, and a decrease of approximately $2.8 million for stock options and RSUs that have fully vested, partially offset by an increase of approximately $1.3 million from new grants.
- a decrease in clinical trial expense of approximately $1.0 million, due primarily to the close out of certain clinical trials;
- a decrease in internal R&D expense of approximately $0.9 million, due primarily to decreases in payroll and payroll related expense related to a reduction in headcount.

These decreases were partially offset by an increase in consultant and contractor expenses of approximately $0.4 million primarily attributable to regulatory-related activities.

Other (expenses) income:

Other income (expenses) in thousands	**For the Three Months Ended September 30,**		**Change**	
			$	**%**
	2019	**2018**	**2019/2018**	**2019/2018**
Interest income	$ 569	$ 590	$ (21)	-3.6%
Interest expense	(3,052)	(3,499)	447	-12.8%
Other income (expenses)	46	(11)	57	-518.2%
	$ (2,437)	$ (2,920)	$ 483	-16.5%

Interest income:

For the three months ended September 30, 2019, we recognized approximately $0.6 million in interest income compared to approximately $0.6 million of interest income for the three months ended September 30, 2018.

Interest expense:

For the three months ended September 30, 2019, we recognized approximately $3.1 million in interest expense, compared to $3.5 million of interest expense for the three months ended September 30, 2018. The decrease in interest expense was primarily the result of decreased borrowings in June 2019.

Nine Months Ended September 30, 2019 Compared to Nine Months Ended September 30, 2018

Total revenue:

For the nine months ended September 30, 2019, total revenue was approximately $209.3 million, compared to $179.9 million for the nine months ended September 30, 2018.

Product revenue, net:

Product revenue, net was approximately $152.9 million for the nine months ended September 30, 2019, compared to $139.4 million for the nine months ended September 30, 2018. The increase in product revenue, net was primarily attributable to a volume increase of approximately 5% in sales of NERLYNX, a 10% increase in gross selling price that occurred in January of 2019, and a 10% increase in gross selling price that occurred in September of 2019, partially offset by an increase in variable consideration of approximately 14% for the nine months ended September 30, 2019 as compared to approximately 8% for the nine months ended September 30, 2018.

License revenue:

License revenue was $56.3 million for the nine months ended September 30, 2019, compared to $40.5 million for the nine months ended September 30, 2018. The increase was primarily due to upfront payments for the satisfaction of performance obligations related to license agreements, as well as the satisfaction of performance-based milestones related to license agreements.

Royalty revenue:

Royalty revenue was $0.2 million for the nine months ended September 30, 2019, compared to no royalty revenue for the nine months ended September 30, 2018. The increase was due to royalty revenue recognized related to the start of product sales by our licensees.

Cost of sales:

For the nine months ended September 30, 2019, cost of sales was approximately $26.7 million compared to $24.3 million for the nine months ended September 30, 2018. The increase in cost of sales was primarily attributable to increased royalty expense due to Pfizer, directly related to the increase in sales of NERLYNX for the nine months ended September 30, 2019 as compared to the nine months ended September 30, 2018.

Selling, general and administrative expenses:

For the nine months ended September 30, 2019, SG&A expenses were approximately $110.4 million, compared to approximately $105.2 million for the nine months ended September 30, 2018. SG&A expenses for the nine months ended September 30, 2019 and 2018 were as follows:

Selling, general, and administrative expenses in thousands	For the Nine Months Ended September 30,		Change	
			$	%
	2019	2018	2019/2018	2019/2018
Payroll and related costs	$ 31,409	$ 32,352	$ (943)	-2.9%
Professional fees and expenses	39,218	28,829	10,389	36.0%
Travel and meetings	8,419	9,272	(853)	-9.2%
Facilities and equipment costs	4,378	4,435	(57)	-1.3%
Other	4,084	3,402	682	20.0%
Stock-based compensation	22,927	26,949	(4,022)	-14.9%
	$ 110,435	$ 105,239	$ 5,196	4.9%

For the nine months ended September 30, 2019, SG&A expenses increased by approximately $5.2 million compared to the same period in 2018, primarily attributable to the following:

- an increase in professional fees and expenses of approximately $10.4 million, comprised of an increase of approximately $10.0 million in legal fees due to insurance reimbursements recorded in the prior period for legal fees in connection with various lawsuits and an increase of approximately $1.0 million in insurance premiums; partially offset by a decrease of approximately $0.6 million for consultancy efforts related to marketing and commercialization support; and
- an increase in other expenses of approximately $0.6 million, comprised of an increase of approximately $0.2 million in office expenses, and approximately $0.4 million in bank fees;

which were partially offset by:

- a decrease of approximately $4.0 million in employee stock-based compensation expense, due primarily to a decrease of approximately $3.6 million from employee turnover, and a decrease of approximately $5.9 million for stock options and RSUs that have fully vested, partially offset by an increase of approximately $5.5 million from new grants;
- a decrease of approximately $0.9 million in payroll and payroll-related expenses primarily due to a decrease in sales commissions; and
- a decrease of approximately $0.9 million in travel and meeting-related expenses.

Research and development expenses:

For the nine months ended September 30, 2019, R&D expenses were approximately $102.6 million, compared to approximately $126.5 million for the nine months ended September 30, 2018. R&D expenses for the nine months ended September 30, 2019 and 2018 were as follows:

Research and development expenses in thousands	For the Nine Months Ended September 30,		Change	
			$	%
	2019	2018	2019/2018	2019/2018
Clinical trial expense	$ 40,665	$ 41,428	$ (763)	-1.8%
Internal R&D	29,485	33,940	(4,455)	-13.1%
Consultant and contractors	9,596	9,768	(172)	-1.8%
Stock-based compensation	22,864	41,393	(18,529)	-44.8%
	$ 102,610	$ 126,529	$ (23,919)	-18.9%

For the nine months ended September 30, 2019, R&D expenses decreased approximately $23.9 million compared to the same period in 2018, primarily attributable to the following:

- a decrease in employee stock-based compensation of approximately $18.5 million, due primarily to a decrease of approximately $12.5 million from employee turnover, and a decrease of approximately $10.6 million for stock options and RSUs that have fully vested, partially offset by an increase of approximately $4.6 million from new grants;
- a decrease in internal R&D expense of approximately $4.5 million, due primarily to a decrease of approximately $4.8 million in payroll and payroll related expense due to reduction in headcount; partially offset by with an increase of approximately $0.3 million in regulatory compliance efforts;
- a decrease in clinical trial expenses of approximately $0.8 million primarily attributable to decreases in CRO-related costs as certain clinical trials are concluding; and
- a decrease in consultant and contractors expense of approximately $0.2 million, due primarily to a decrease of approximately $0.9 million in consulting fees for clinical research associates for certain clinical trials, offset by an increase of approximately $0.7 million in consulting fees for regulatory related activities.

Other (expenses) income:

Other income (expenses) in thousands	**For the Nine Months Ended September 30,**		**Change**	
			$	**%**
	2019	**2018**	**2019/2018**	**2019/2018**
Interest income	$ 2,349	$ 1,093	$ 1,256	114.9%
Interest expense	(11,943)	(7,165)	(4,778)	66.7%
Legal verdict expense	(16,350)	—	(16,350)	100.0%
Loss on debt extinguishment	(8,103)	—	(8,103)	100.0%
Other income (expenses)	31	(690)	721	-104.5%
	$ (34,016)	$ (6,762)	$ (27,254)	403.0%

Interest income:

For the nine months ended September 30, 2019, we recognized approximately $2.3 million in interest income compared to approximately $1.1 million of interest income for the nine months ended September 30, 2018. The increase in interest income reflects more cash in money market accounts and “high yield” savings accounts in 2019 compared to 2018.

Interest expense:

For the nine months ended September 30, 2019, we recognized approximately $11.9 million in interest expense, compared to $7.2 million of interest expense for the nine months ended September 30, 2018. The increase in interest expense was the result of increased borrowings as well as a higher interest rate.

Legal verdict expense:

For the nine months ended September 30, 2019, we recognized approximately $16.4 million in legal verdict expense related to the *Eshelman v. Puma Biotechnology, Inc., et al.* verdict. The legal verdict expense of $16.4 million is the result of our estimate of the total damages payable in the matter of $22.4 million, net of $6.0 million in insurance reimbursements.

Loss on debt extinguishment:

For the nine months ended September 30, 2019, we recognized approximately $8.1 million in loss on debt extinguishment related to the fees paid in connection with our debt refinancing during the second quarter of 2019 that resulted in the reduction of our long-term debt by approximately $55.0 million.

Other expense:

For the nine months ended September 30, 2018, we recognized approximately $0.7 million in other expense, which primarily consisted of fees from the modification of debt.

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of September 30, 2019 and December 31, 2018, and for the nine months ended September 30, 2019 and 2018, and is intended to supplement the more detailed discussion that follows:

Liquidity and capital resources (in thousands)	September 30, 2019	December 31, 2018
Cash and cash equivalents	$ 58,904	$ 108,419
Marketable securities	$ 51,535	$ 57,002
Working capital	$ 62,752	$ 135,888
Stockholders' equity	$ 17,180	$ 34,306

	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
Cash provided by (used in):		
Operating activities	$ 20,810	$ (31,152)
Investing activities	5,595	(60,205)
Financing activities	(67,066)	77,959
Decrease in cash and cash equivalents	$ (40,661)	$ (13,398)

Operating Activities:

For the nine months ended September 30, 2019, we reported a net loss of approximately $64.4 million, compared to approximately $82.9 million for the same period in 2018. Additionally, cash provided by operating activities for the nine months ended September 30, 2019 was approximately $20.8 million compared to approximately $31.2 million of cash used in operating activities for the same periods in 2018, respectively.

Cash provided by operating activities for the nine months ended September 30, 2019 consisted of a net loss of approximately $64.4 million, a decrease in prepaid expenses and other of approximately $2.9 million, a decrease in other current assets of approximately $1.5 million, an increase of approximately $30.3 million in accrued expenses, an increase of approximately $9.0 million in a post-marketing commitment liability, and approximately $60.0 million of non-cash items, such as stock-based compensation, depreciation and amortization, and debt extinguishment fees; offset by an increase in net accounts receivable of approximately $6.4 million, an increase in inventory of approximately $0.5 million, and a decrease in accounts payable of approximately $11.6 million.

Cash used in operating activities for the nine months ended September 30, 2018 consisted of a net loss of approximately $82.9 million, an increase in net accounts receivable of approximately $10.1 million, an increase in other current assets of approximately $11.5 million, an increase of approximately $10.9 million in accrued expenses and an increase of approximately $0.8 million in inventory, offset by a decrease of approximately $11.4 million in accounts payable, $0.2 million decrease in prepaid expenses and other and $73.9 million of non-cash items such as stock-based compensation, depreciation and amortization, and loss on modification of debt.

Investing Activities:

During the nine months ended September 30, 2019, net cash provided by investing activities was approximately $5.6 million, compared to net cash used in investing activities of $60.2 million for the same period in 2018. Net cash provided by investing activities during the nine months ended September 30, 2019 consisted of approximately $133.6 million of sales or maturities of available-for-sale securities, offset by $128.0 million of cash invested in available-for-sale securities. Net cash used in investing activities during the nine months ended September 30, 2018 was made up of approximately $71.1 million of cash invested in available-for-sale securities, offset by approximately $11.5 million of sales or maturities of available-for-sales securities, and approximately $0.3 million of cash used to purchase property and equipment.

Financing Activities:

During the nine months ended September 30, 2019, cash used in financing activities was approximately $67.1 million, which consisted of approximately $80.0 million in debt repayments, approximately $7.8 million in debt extinguishment costs and approximately $5.6 million in debt issuance costs, offset by approximately $25.0 million in proceeds from long-term debt and approximately $1.3 million in proceeds from the exercise of stock options. During the same period in 2018, cash provided by financing activities was approximately $78.0 million, which consisted of approximately $75.0 million of incremental proceeds from long-term debt, and approximately $7.2 million in net proceeds from the exercise of stock options, partially offset by approximately $4.2 million of payments related to debt issuance costs.

Loan and Security Agreement:

In October 2017, we entered into the Original Credit Facility with SVB, as administrative agent, and the Original Lenders. Pursuant to the terms of the credit facility provided for by the original loan and security agreement, we borrowed $50 million. In May 2018, we entered into 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. The Company was 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 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 subsidiary and any subsidiaries we create in the future. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and satisfy certain requirements regarding deposit accounts. We must also achieve certain product revenue targets, measured as of the last day of each fiscal quarter on a trailing year to date basis, for the periods ending June 30, 2019, September 30, 2019 and December 31, 2019. 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 September 30, 2019, there was $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 revenue until the third quarter of 2017. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our planned product development efforts, our clinical trials, our R&D efforts and our commercialization efforts. Given the current and desired pace of clinical development of our product candidates, we expect R&D spending to decline over the next 12 months.

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

We may choose to begin new R&D efforts or we may choose to launch additional marketing efforts. These efforts may require funding in addition to the cash and cash equivalents totaling approximately $58.9 million and $51.5 million in marketable securities available at September 30, 2019. While our consolidated financial statements have been prepared on a going concern basis, we expect to continue incurring significant losses for the foreseeable future and will continue to remain dependent on our ability to obtain sufficient funding to sustain operations and successfully commercialize neratinib. While we have been successful in raising financing in the past, there can be no assurance that we will be able to do so in the future. Our ability to obtain funding may be adversely impacted by uncertain market conditions, unfavorable decisions of regulatory authorities or adverse clinical trial results. The outcome of these matters cannot be predicted at this time. We believe that our existing cash and cash equivalents and marketable securities as of September 30, 2019 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 the Quarterly Report on Form 10-Q.

In addition, we have based our estimate of capital needs on assumptions that may prove to be wrong. Changes may occur that would consume our available capital faster than anticipated, including changes in and progress of our development activities, the impact of commercialization efforts, acquisitions of additional drug candidates and changes in regulation. Potential sources of financing include strategic relationships, public or private sales of equity or debt and other sources of funds. We may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. 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 and nine months ended September 30, 2019, stock-based compensation represented approximately 19.9% and 21.5% of our operating expenses, respectively, and 32.1% and 29.5% for the same period in 2018. 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 September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
GAAP net loss	$ (16,885)	$ (14,201)	$ (64,396)	$ (82,880)
Adjustments:				
Stock-based compensation -				
Selling, general and administrative	5,600	9,412 (1)	22,927	26,949 (1)
Research and development	6,613	11,395 (2)	22,864	41,394 (2)
Non-GAAP adjusted net loss	$ (4,672)	$ 6,606	$ (18,605)	$ (14,537)
GAAP net loss per share—basic	$ (0.44)	$ (0.37)	$ (1.67)	$ (2.19)
Adjustment to net loss (as detailed above)	0.32	0.54	1.19	1.81
Non-GAAP adjusted basic net (loss) income per share	$ (0.12)	$ 0.17 (3)	$ (0.48)	$ (0.38) (4)
GAAP net loss per share—diluted	$ (0.44)	$ (0.36)	$ (1.67)	$ (2.19)
Adjustment to net loss (as detailed above)	0.32	0.52	1.19	1.81
Non-GAAP adjusted diluted net (loss) income per share	$ (0.12) (5)	$ 0.16 (6)	$ (0.48)	$ (0.38) (7)

(1) To reflect a non-cash charge to operating expense for selling, general, and administrative stock-based compensation.
(2) To reflect a non-cash charge to operating expense for research and development stock-based compensation.
(3) Non-GAAP adjusted basic net loss per share was calculated based on 38,893,757 and 38,043,174 weighted-average shares of common stock outstanding for the three months ended September 30, 2019 and 2018, respectively.
(4) Non-GAAP adjusted basic net loss per share was calculated based on 38,675,961 and 37,855,249 weighted-average shares of common stock outstanding for the nine months ended September 30, 2019 and 2018, respectively.
(5) Potentially dilutive common stock equivalents (stock options, restricted stock units and warrants) were not included in this non-GAAP adjusted diluted net loss per share for the three months ended September 30, 2019 as these shares would be considered anti-dilutive.
(6) Non-GAAP adjusted diluted net income per share was calculated based on 39,677,446 weighted average shares of common stock outstanding and potentially dilutive common stock equivalents (stock options, restricted stock units and warrants) for the three months ended September 30, 2018.
(7) 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 nine months ended September 30, 2019 and 2018, respectively, as these shares would be considered anti-dilutive.

Off-Balance Sheet Arrangements

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

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Some of the securities that we invest in have market risk in that a change in prevailing interest rates may cause the principal amount of the cash equivalents to fluctuate. Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash and cash equivalents. We invested our excess cash primarily in cash equivalents such as money market investments as of September 30, 2019. The primary objectives of our investment activities are to ensure liquidity and to preserve principal while at the same time maximizing the income we receive from our cash and cash equivalents without significantly increasing risk. Additionally, we established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity.

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

We also have interest rate exposure as a result of borrowings outstanding under our loan and security agreement. As of September 30, 2019, 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 September 30, 2019. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that these disclosure controls and procedures were effective as of September 30, 2019.

Changes in Internal Control over Financial Reporting

Effective January 1, 2019, we adopted Accounting Standards Codification 842, Leases (Topic 842). As a result, we have made changes to certain internal controls over financial reporting to address risks associated with the required lease accounting and disclosure requirements. This includes the enhancement of our lease evaluation processes and the implementation of controls to address risks associated with the calculation of right-of-use assets and corresponding lease liabilities. There were no other changes in our internal control over financial reporting that occurred during the three months ended September 30, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

Hsu v. Puma Biotechnology, Inc.,

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

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. Plaintiff has since filed motions seeking attorneys' fees and pre-judgment interest, which if granted could increase the judgment amount. We strongly disagree with the verdict and, on April 22, 2019, filed a motion for a new trial or, in the alternative, a reduced damages award. If the verdict is upheld, pending the outcome of that motion, we intend to appeal the verdict. We estimate the high end of potential damages in the matter could be approximately $26.3 million; however, the actual amount of damages payable by us is still uncertain and will be ascertained only after completion of post-trial proceedings and the exhaustion of any appeals, and such amounts 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, 2018, which was filed with the SEC on March 1, 2019, we identified important factors that could affect our financial performance and could cause our actual results for future periods to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statements made in this Form 10-Q. There has been no material change in our risk factors subsequent to the filing of our Annual Report. However, the risks described in our Annual Report are not the only risks we face. Additional risks and uncertainties that we currently deem to be immaterial or not currently known to us, as well as other risks reported from time to time in our reports to the SEC, also could cause our actual results to differ materially from our anticipated results or other expectations.

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

Recent Sales of Unregistered Securities

We did not sell any of our equity securities without registration under the Securities Act of 1933, as amended, during the three months ended September 30, 2019.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Neither we nor any "affiliated purchasers" within the definition of Rule 10b-18(a)(3) promulgated under the Exchange Act made any purchases of our equity securities during the quarter ended September 30, 2019.

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+	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 September 30, 2019
31.2+	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, with respect to the registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2019
32.1++	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2++	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS+	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

SIGNATURES

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

PUMA BIOTECHNOLOGY, INC.

Date: November 7, 2019

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

Date: November 7, 2019

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

PUMA BIOTECHNOLOGY, INC.
NON-EMPLOYEE DIRECTOR COMPENSATION PROGRAM

(EFFECTIVE SEPTEMBER 10, 2019)

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:	
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 September 30, 2019;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2019

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

Exhibit 31.2

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

I, Maximo F. Nougues, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended September 30, 2019;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2019

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

Exhibit 32.1

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

The following certification is being furnished solely to accompany the Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended September 30, 2019, pursuant to 18 U.S.C. § 1350 and in accordance with SEC Release No. 33-8238. This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference in any filing of Puma Biotechnology, Inc. under the Securities Act of 1933, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Certification of Principal Executive Officer

I, Alan H. Auerbach, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended September 30, 2019, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of Puma Biotechnology, Inc.

Date: November 7, 2019

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

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

Exhibit 32.2

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

The following certification is being furnished solely to accompany the Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended September 30, 2019, pursuant to 18 U.S.C. § 1350 and in accordance with SEC Release No. 33-8238. This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference in any filing of Puma Biotechnology, Inc. under the Securities Act of 1933, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Certification of Principal Financial Officer

I, Maximo F. Nougues, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended September 30, 2019, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of Puma Biotechnology, Inc.

Date: November 7, 2019

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

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