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, 2017

OR

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

For the transition period from _____to _____

Commission File Number: 001-35703

PUMA BIOTECHNOLOGY, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	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. 37,529,536 shares of Common Stock, par value $0.0001 per share, were outstanding as of November 6, 2017.

PUMA BIOTECHNOLOGY, INC.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

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

- the commercialization and availability 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;
- our ability to market any of our products;
- our history of operating losses;
- our expectations regarding our costs and expenses;
- our anticipated capital requirements and estimates regarding our needs for additional financing;
- our ability to compete against other companies and research institutions;
- our ability to secure adequate protection for our intellectual property;
- our intention and ability to vigorously defend against a securities class action lawsuit, derivative lawsuits and a defamation lawsuit;
- our ability to attract and retain key personnel; and
- our ability to obtain adequate financing.

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

Part I – FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2017	December 31, 2016 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 79,717	$ 194,494
Marketable securities	26,620	34,982
Accounts receivable, net	3,890	—
Inventory	89	—
Prepaid expenses and other, current	9,281	6,998
Total current assets	119,597	236,474
Property and equipment, net	4,714	5,153
Prepaid expenses and other, long-term	3,851	6,846
Intangible assets, net	49,379	—
Restricted cash	4,317	4,317
Total assets	$ 181,858	$ 252,790
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 17,644	$ 20,035
Accrued expenses	79,608	17,426
Total current liabilities	97,252	37,461
Deferred rent	5,438	5,505
Total liabilities	102,690	42,966
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Common stock - $.0001 par value; 100,000,000 shares authorized; 37,384,975 shares issued and outstanding at September 30, 2017 and 36,826,010 issued and outstanding at December 31, 2016	4	4
Additional paid-in capital	1,109,212	1,006,344
Receivable from exercise of stock options	(5,653)	—
Accumulated other comprehensive loss	(7)	(13)
Accumulated deficit	(1,024,388)	(796,511)
Total stockholders' equity	79,168	209,824
Total liabilities and stockholders' equity	$ 181,858	$ 252,790

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2017	2016	2017	2016
Product Revenue, net	$ 6,077	$ —	$ 6,077	$ —
Operating costs and expenses:				
Cost of sales	$ 1,526	$ —	$ 1,526	$ —
Selling, general and administrative	32,489	14,022	75,819	37,326
Research and development	49,502	51,977	157,556	166,400
Total operating expense	83,517	65,999	234,901	203,726
Loss from operations	(77,440)	(65,999)	(228,824)	(203,726)
Other (expenses) income:				
Interest income	305	214	1,035	756
Other (expenses) income	(45)	4	(88)	(380)
Total other (expenses) income	260	218	947	376
Net loss	$ (77,180)	$ (65,781)	$ (227,877)	$ (203,350)
Net loss applicable to common stock	$ (77,180)	$ (65,781)	$ (227,877)	$ (203,350)
Net loss per common share—basic and diluted	$ (2.07)	$ (2.02)	$ (6.15)	$ (6.26)
Weighted-average common shares outstanding—basic and diluted	37,214,002	32,497,168	37,046,765	32,489,584

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2017	2016	2017	2016
Net loss	$ (77,180)	$ (65,781)	$ (227,877)	$ (203,350)
Other comprehensive income (loss)				
Unrealized gain (loss) on available-for-sale securities	18	(28)	6	150
Comprehensive loss	$ (77,162)	$ (65,809)	$ (227,871)	$ (203,200)

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

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

	Common Stock		Additional Paid-in Capital	Receivables from the Exercises of Options	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount					
Balance at December 31, 2016	36,826,010	$ 4	$ 1,006,344	$ —	$ (13)	$ (796,511)	$ 209,824
Stock-based compensation	—	—	83,213	—	—	—	83,213
Exercises of stock options/issuances of RSUs	558,965	—	19,655	(5,653)	—	—	14,002
Unrealized gain on available-for-sale securities	—	—	—	—	6	—	6
Net loss	—	—	—	—	—	(227,877)	(227,877)
Balance at September 30, 2017	37,384,975	$ 4	$ 1,109,212	$ (5,653)	$ (7)	$ (1,024,388)	$ 79,168

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

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

	For the Nine Months Ended	
	2017	2016
Operating activities:		
Net loss	$ (227,877)	$ (203,350)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,451	565
Built-out allowance received from landlord	—	2,997
Stock-based compensation	83,213	87,990
Disposal of leasehold improvements	—	368
Changes in operating assets and liabilities:		
Accounts receivable, net	(3,890)	—
Inventory	(89)	—
Other receivables	—	(1,179)
Prepaid expenses and other	712	2,832
Intangible assets, net		—
Accounts payable	(2,496)	3,075
Accrued expenses	12,182	2,082
Accrual of deferred rent	(67)	3,891
Net cash used in operating activities	(136,861)	(100,729)
Investing activities:		
Purchase of property and equipment	(286)	(3,730)
Restricted cash	—	(3)
Expenditures for leasehold improvements	—	(2,997)
Purchase of available-for-sale securities	(79,728)	(81,794)
Sale/maturity of available-for-sale securities	88,096	209,874
Net cash provided by investing activities	8,082	121,350
Financing activities:		
Net proceeds from the exercise of options	14,002	351
Net cash provided by financing activities	14,002	351
Net (decrease) increase in cash and cash equivalents	(114,777)	20,972
Cash and cash equivalents, beginning of period	194,494	31,569
Cash and cash equivalents, end of period	$ 79,717	$ 52,541
Supplemental disclosures of non-cash investing and financing activities:		
Property and equipment purchases in accounts payable	$ 105	$ —
Licensor fee due in accrued expenses	$ 50,000	$ —
Receivables related to stock option exercises	$ 5,653	$ —

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

Note 1—Business and Basis of Presentation:

Business:

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

In November 2012, the Company established and incorporated Puma Biotechnology Ltd., a wholly owned subsidiary, for the sole purpose of serving as Puma's legal representative in the United Kingdom and the European Union in connection with Puma's clinical trial activity in those countries.

Basis of Presentation:

The Company is focused on developing and commercializing neratinib for the treatment of patients with human epidermal growth factor receptor type 2, or HER2-positive, breast cancer, HER2 mutated non-small cell lung cancer, HER2-negative breast cancer that has a HER2 mutation and other solid tumors that have an activating mutation in HER2. The Company has reported a net loss of approximately $77.2 million and $227.9 million for the three and nine months ended September 30, 2017, and negative cash flows from operations of approximately $136.9 million for the nine months ended September 30, 2017. Management believes that the Company will continue to incur net losses and negative net cash flows from operating activities through the drug development process and early commercialization.

The accompanying unaudited condensed consolidated interim financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP, pursuant to the rules and regulations of the Securities and Exchange Commission, or the SEC, for interim financial information. Accordingly, the unaudited condensed consolidated financial statements do not include all information and footnotes required by GAAP for complete annual financial statements. In the opinion of management, the accompanying unaudited condensed consolidated interim financial statements reflect all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation. Interim operating results are not necessarily indicative of results that may be expected for the year ending December 31, 2017, or for any subsequent period. These unaudited condensed consolidated interim financial statements should be read in conjunction with the Company's audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2016. The condensed consolidated balance sheet at December 31, 2016 has been derived from the audited consolidated financial statements included in the Annual Report on Form 10-K for the fiscal year ended December 31, 2016.

The Company has incurred significant operating losses since its inception, which raises substantial doubt about its ability to continue as a going concern. On July 17, 2017, the Company received U.S. Food and Drug Administration, or FDA, approval for its first product, NERLYNX® (neratinib), formerly known as PB272 (neratinib (oral)), for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer following adjuvant trastuzumab-based therapy. NERLYNX recently became available by prescription in the United States, and the Company has commenced commercialization. The Company is exploring methods by which to commercially launch neratinib in the European Union should approval be granted by the European Medicines Agency, or EMA. Commercialization in the United States, and if approved, in the European Union, may require funding in addition to the cash and cash equivalents and marketable securities totaling approximately $106.3 million available at September 30, 2017. While the consolidated financial statements have been prepared on a going concern basis, the Company continues to remain dependent on its ability to obtain sufficient funding to sustain operations and successfully commercialize neratinib in the United States, and, if approved, launch in the European Union. While the Company has been successful in raising financing in the past, there can be no assurance that it will be able to do so in the future. The Company's ability to obtain funding may be adversely impacted by uncertain market conditions, unfavorable decisions of regulatory authorities or adverse clinical trial results. The outcome of these matters cannot be predicted at this time. The Company's continued operations will depend on its ability to successfully commercialize NERLYNX, the Company's only product, and to raise funds through various potential sources, such as equity and debt financing.

Since its inception through September 30, 2017, the Company's financing was primarily through public offerings of Company common stock and private equity placements. The Company sold shares of its common stock through an underwritten public offering

in October 2016 (see Note 6 to the Annual Report on Form 10-K for the year ended December 31, 2016). As a result, the Company received net proceeds of approximately $161.9 million. The Company may need additional financing bef ore it can achieve profitability, if ever. There can be no assurance that additional capital will be available on favorable terms or at all or that any additional capital that the Company is able to obtain will be sufficient to meet its needs. If it is u nable to raise additional capital, the Company could likely be forced to curtail desired development activities, which will delay the development of its product candidates.

Note 2—Significant Accounting Policies:

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

Use of Estimates:

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect reported amounts of assets and liabilities, and disclosure of contingent assets and liabilities at the date of the balance sheet, and reported amounts of expenses for the period presented. Accordingly, actual results could differ from those estimates. Significant estimates include accrued expenses for the cost of services provided by consultants who manage clinical trials and conduct research and clinical trials on behalf of the Company that are billed on a delayed basis. As the actual costs become known, the Company adjusts its estimated cost in that period. The value of stock-based compensation includes estimates based on future events, which are difficult to predict. It is at least reasonably possible that a change in the estimates used to record accrued expenses and to value the stock-based compensation will occur in the near term.

Principles of Consolidation:

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

Cash and Cash Equivalents:

The Company considers all highly liquid investments with original maturities of three months or less to be cash equivalents. Cash equivalents are carried at cost, which approximates fair value.

Investment Securities:

The Company classifies all investment securities (short term) as available-for-sale, as the sale of such securities may be required prior to maturity to implement management’s strategies. These securities are carried at fair value, with the unrealized gains and losses reported as a component of accumulated other comprehensive income (loss) in stockholders’ equity until realized. Realized gains and losses from the sale of available-for-sale securities, if any, are determined on a specific identification basis. A decline in the market value of any available-for-sale security below cost that is determined to be other than temporary results in a revaluation of its carrying amount to fair value. The impairment is charged to earnings and a new cost basis for the security is established.

Accounts Receivable:

Accounts receivable are recorded net of customer allowances for distribution fees, prompt payment discounts, chargebacks, and doubtful accounts. Allowances for distribution fees, prompt payment discounts and chargebacks are based on contractual terms. The Company estimates the allowance for doubtful accounts based on existing contractual payment terms, actual payment patterns of its customers and individual customer circumstances. At September 30, 2017, the Company determined that an allowance for doubtful accounts was not required. No accounts were written off during the periods presented.

License Fees and Royalties:

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.

In connection with the FDA approval of NERLYNX in July 2017, the Company triggered a one-time milestone payment pursuant to its 2014 licens e agreement with Pfizer Inc., or the Licensor. The Company capitalized the milestone payment as an intangible asset and is amortizing the asset on a straight-line basis over the estimated useful life of the licensed patent through 2030. The Company recorde d amortization expense related to its intangible asset of $0. 6 million for the three months ended September 30, 2017. As of September 30, 2017, estimated future amortization expense related to the Company's intangible asset was $1.0 million for the remaind er of 2017, approximately $3.9 million for each year starting 2018 through 2029, and $1.0 million for 2030.

Royalties incurred in connection with the Company's license agreement with the Licensor, as disclosed in Note 9-Commitments and Contingencies, are expensed to cost of sales as revenue from product sales is recognized.

Intangible Assets:

The Company maintains definite-lived intangible assets related to the Licensor agreement. 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.

The Company assesses its intangible assets for impairment if indicators are present or changes in circumstance suggest that impairment may exist. Events that could result in an impairment, or trigger an interim impairment assessment, include the receipt of additional clinical or nonclinical data regarding one of the Company's drug candidates or a potentially competitive drug candidate, changes in the clinical development program for a drug candidate, or new information regarding potential sales for the drug. If impairment indicators are present or changes in circumstance suggest that impairment may exist, the Company performs a recoverability test by comparing the sum of the estimated undiscounted cash flows of each intangible asset to its carrying value on the condensed 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.

Inventory:

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

The Company capitalizes inventory costs associated with the Company's products after regulatory approval, if any, when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. Inventory acquired prior to receipt of marketing approval of a product candidate is expensed as research and development expense as incurred. Inventory that can be used in either the production of clinical or commercial product is expensed as research and development expense when selected for use in a clinical trial. Starter kits, provided to patients prior to insurance approval, are expensed by the Company to sales and marketing expense as incurred.

Revenue Recognition:

The Company adopted Accounting Standards Codification ("ASC") Topic 606 - Revenue from Contracts with Customers ("Topic 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 Topic 606, an entity recognizes revenue when its customer obtains control of the promised goods or services, in an amount that reflects the consideration which the entity expects to be entitled in exchange for those goods or services. The Company had no contracts with customers until the FDA approved NERLYNX on July 17, 2017. Subsequent to receiving FDA approval, the Company entered into a limited number of arrangements with specialty pharmacies ("SPs") and specialty distributors ("SDs") in the U.S. (collectively, its "Customers") 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 Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer, (ii) identify the performance obligations in the contract,

(iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, and (v) recognize 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 Topic 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 Topic 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 transac tion 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 SPs and SDs in the U.S. (collectively, its "Customers"). These Customers subsequently resell the Company's products to patients and certain medical centers or hospitals. In addition to distribution agreements with 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 Customer obtains control of the Company's product, which occurs at a point in time (upon delivery). Product revenue is recorded net of applicable reserves for variable consideration, including discounts and allowances. The Company's payment terms range between 10 and 60 days.

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

If taxes should be collected from 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, 2017.

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 amounts earned, or to be claimed on the related sales, and are classified as reductions of accounts receivable (if the amount is payable to the Customer) or a current liability (if the amount is payable to a party other than a Customer). These estimates take into consideration a range of possible outcomes which are probability-weighted in accordance with the expected value method in 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 which is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. The Company's analyses also contemplated application of the constraint in accordance with the guidance, under which it determined a material reversal of revenue would not occur in a future period for the estimates detailed below as of September 30, 2017 and, therefore, the transaction price was not reduced further during the three months ended September 30, 2017. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Trade Discounts and Allowances:

The Company generally provides Customers with discounts which include incentive fees that are explicitly stated in the Company's contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized. In addition, the Company compensates (through trade discounts and allowances) its Customers for sales order management, data, and distribution services. However, the Company has determined such services received to date are not distinct from the Company's sale of products to the Customer and, therefore, these payments have been recorded as a reduction of revenue within the statement of operations and

comprehensive loss through September 30, 2017, as well as a reduction to trade receivables, net on the condensed consolidated balance sheets.

Product Returns:

Consistent with industry practice, the Company offers the SPs and SDs limited product return rights for damages and expiring product, provided it is within a specified period around the product expiration date as set forth in the applicable individual distribution agreement. The Company estimates the amount of its product sales that may be returned by its Customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized, as well as reductions to trade receivables, net on the condensed consolidated balance sheets. The Company currently estimates product return liabilities using available industry data and its own sales information, including its visibility into the inventory remaining in the distribution channel. The Company has not received any returns to date and believes that returns of its products will 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 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. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and trade receivables, net. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider by Customers, and the Company generally issues credits for such amounts within a few weeks of the Customer's notification to the Company of the resale. Reserves for chargebacks consist of credits that the Company expects to issue for units that remain in the distribution channel inventories 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 credit.

Government Rebates:

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

Payor Rebates:

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

Other Incentives:

Other incentives which 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 inventories 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 condensed consolidated balance sheets.

Assets Measured at Fair Value on a Recurring Basis:

Accounting Standards Codification, or 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 pr incipal 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, wh ich 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 onl y 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 value s. 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, 2017 and December 31, 2016, 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, 2017	**Level 1**	**Level 2**	**Level 3**	**Total**
Cash equivalents	$ 68,911	$ —	$ —	$ 68,911
Marketable securities - corporate bonds	—	26,620	—	26,620
	$ 68,911	$ 26,620	$ —	$ 95,531

December 31, 2016	**Level 1**	**Level 2**	**Level 3**	**Total**
Cash equivalents	$ 188,543	$ —	$ —	$ 188,543
Commercial paper	—	5,998	—	5,998
Marketable securities - corporate bonds	—	28,984	—	28,984
	$ 188,543	$ 34,982	$ —	$ 223,525

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 Company invests its excess cash in commercial paper and debt instruments of corporations. As of September 30, 2017, the Company's short-term investments had a weighted average maturity of less than one year.

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

September 30, 2017	**Maturity (in years)**	**Amortized cost**	**Unrealized Gains**	**Unrealized Losses**	**Estimated fair value**
Cash equivalents		$ 68,911	$ —	$ —	$ 68,911
Marketable securities - corporate bonds	Less than 1	26,620	—	(7)	26,613
		$ 95,531	$ —	$ (7)	$ 95,524

December 31, 2016	**Maturity (in years)**	**Amortized cost**	**Unrealized Gains**	**Unrealized Losses**	**Estimated fair value**
Cash equivalents		$ 188,543	$ —	$ —	$ 188,543
Commercial paper	Less than 1	5,998	—	—	5,998
Marketable securities - corporate bonds	Less than 1	28,984	—	(13)	28,971
		$ 223,525	$ —	$ (13)	$ 223,512

Concentration of Risk:

Financial instruments, which potentially subject the Company to concentrations of credit risk, principally consist of cash and cash equivalents. The Company's cash and cash equivalents in excess of the Federal Deposit Insurance Corporation and the Securities Investor Protection Corporation insured limits at September 30, 2017, were approximately $85.4 million. The Company does not

believe it is exposed to any significant credit risk due to the quality 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 Corporation and Moody's Investors Service at the time of purchase.

Property and Equipment:

Property and equipment are recorded at cost and depreciated over estimated useful lives ranging from three to five years using the straight-line method. Leasehold improvements are recorded at cost and amortized over the shorter of their useful lives or the term of the lease by use of the straight-line method. Maintenance and repair costs are charged to operations as incurred.

The Company assesses the impairment of long-lived assets, primarily property and equipment, whenever events or changes in business circumstances indicate that carrying amounts of the assets may not be fully recoverable. When such events occur, management determines whether there has been impairment by comparing the asset's carrying value with its fair value, as measured by the anticipated undiscounted net cash flows of the asset. Should impairment exist, the asset is written down to its estimated fair value. The Company has not recognized any impairment losses through September 30, 2017.

Research and Development Expenses:

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

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

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

Stock-Based Compensation:

Stock option awards:

ASC 718, *Compensation — Stock Compensation* , or ASC 718, requires the fair value of all share-based payments to employees, including grants of stock options, to be recognized in the statement of operations over the requisite service period. Under ASC 718, employee option grants are generally valued at the grant date and those valuations do not change once they have been established. The fair value of each option award is estimated on the grant date using the Black-Scholes Option Pricing Method. As allowed by ASC 718 for companies with a short period of publicly traded stock history, the Company's estimate of expected volatility is based on the average expected volatilities of a sampling of seven companies with similar attributes to the Company, including industry, stage of life cycle, size and financial leverage. The risk-free rate for periods within the contractual life of the 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, the Company uses the simplified method to determine the expected life of the option grants.

Restricted stock units:

The 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).

Net Loss per Common Share:

Basic net loss per common share is computed by dividing net loss applicable to common stockholders by the weighted average number of common shares outstanding during the periods presented as required by ASC 260, *Earnings per Share* . Diluted earnings per common share are the same as basic earnings per common share because the assumed exercise of the Company's outstanding options are anti-dilutive. For the three and nine months ended September 30, 2017, potentially dilutive securities excluded from the calculations were 6,295,192 shares issuable upon exercise of options, 2,116,250 shares issuable upon exercise of a warrant, and 956,060 shares underlying restricted stock units that are subject to vesting and are antidilutive. For the three and nine months ended September 30, 2016, potentially dilutive securities excluded from the earnings per common share calculation were 5,730,151 issuable upon exercise of options, 9,469 issuable as performance shares and 2,116,250 shares issuable upon exercise of a warrant.

Deferred Rent:

The Company has entered into operating lease agreements for its corporate offices in Los Angeles and South San Francisco that contain provisions for future rent increases, leasehold improvement allowances and rent abatements. The Company records monthly rent expense equal to the total of the payments due over the lease term, divided by the number of months of the lease term. The difference between the rent expense recorded and the amount paid is credited or charged to deferred rent, which is reflected as a separate line item in the accompanying unaudited condensed consolidated balance sheets. Additionally, the Company recorded as deferred rent the cost of the leasehold improvements paid by the landlord, which is amortized on a straight-line basis over the term of the lease.

Issuance of Common Stock Upon Exercise of Stock Option Grants:

When a stock option grant is exercised, the Company notifies its transfer agent to release the required number of shares of common stock from the reserve for the Puma Biotechnology, Inc. 2011 Incentive Award Plan, as amended, or the 2011 Plan. The Company records the transaction for the cash received and the issuance of common shares. Should there be a delay in the cash receipts due to the settlement period, the Company records a receivable from the exercise of an option as a reduction of stockholders' equity on the unaudited condensed consolidated balance sheet.

Recently Issued Accounting Standards:

In May 2014, the Financial Accounting Standards Board, FASB, issued a new accounting standard that amends the guidance for the recognition of revenue from contracts with customers to transfer goods and services. The FASB has subsequently issued additional, clarifying standards to address issues arising from implementation of the new revenue recognition standard. The new revenue recognition standard and clarifying standards are effective for interim and annual periods beginning on January 1, 2018, but could have been adopted early beginning January 1, 2017. The Company has chosen to adopt this standard in 2017 as it began to generate revenue. The Company has also identified and implemented changes to its accounting policies, business processes, and internal controls to support the new accounting and disclosure requirements.

In February 2016, the FASB issued Accounting Standards Update, or ASU, No. 2016-02, *Leases* . The amendments in ASU 2016-02 will require organizations that lease assets, with lease terms of more than 12 months, to recognize on their balance sheet the assets and liabilities for the rights and obligations created by those leases. Consistent with current GAAP, the recognition, measurement, and presentation of expenses and cash flows arising from a lease by a lessee primarily will depend on its classification as a finance or operating lease. However, unlike current GAAP which requires only capital leases to be recognized on the balance sheet, ASU No. 2016-02 will require both types of leases to be recognized on the balance sheet. ASU 2016-02 will be effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. The Company is currently in the process of evaluating the impact of ASU 2016-02 on the Company's outstanding leases and expects that adoption will have an impact on the consolidated balance sheets related to recording right-of-use assets and corresponding lease liabilities.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation – Stock Compensation: Improvements to Employee Share-Based Payment Accounting,* which was intended to simplify various aspects of accounting for sh are-based payment transactions. The new guidance requires immediate recognition of all excess tax benefits and deficiencies in the income statement; requires classification of excess tax benefits as an operating activity as opposed to a financing activity in the statements of cash flows; requires the classification of cash paid by an employer when directly withholding shares for tax-withholding purposes be classified as a financing activity on the statements of cash flows; and allows the Company to make an accounting policy election to either estimate the number of awards expected to vest or account for forfeitures when they occur. The standard is effective for annual reporting periods beginning after December 15, 2016, and interim periods within those annua l reporting periods. The Company applied this standard in the first quarter of 2017 using the prospective method of adoption. In conjunction with this adoption, the Company applied an accounting policy election to estimate forfeitures and then true up actu al forfeitures as they occur. Because this treatment was in line with the Company's current treatment of forfeitures, the impact was insignificant as of September 30, 2017. Additionally, the Company believes there is no effect on its consolidated financi al statements from either the new guidance of immediate recognition of all excess tax benefits and deficiencies in the income statement or the requirement to classify excess tax benefits as an operating activity, as opposed to a financing activity, in the statements of cash flows, as the Company currently has a full valuation for any deferred tax asset; therefore, there would be no net effect on the Company's consolidated financial statements. Finally, the Company does not directly withhold shares for tax- withholding purposes; therefore, this change has no net effect on its consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows* (*Topic 230*) *: Classification of Certain Cash Receipts and Cash Payments* (*a consensus of the Emerging Issues Task Force*), which addresses the diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. This update addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice. ASU 2016-15 will be effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. The Company is currently evaluating the impact of adopting ASU 2016-15 on its consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows* (*Topic 230*): *Restricted Cash* that changes the presentation of restricted cash and cash equivalents on the statement of cash flows. Restricted cash and restricted cash equivalents will be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. This amendment is effective for the Company in the fiscal year beginning December 15, 2017, but early adoption is permissible. The Company is currently evaluating the effect that the adoption of ASU 2016-18 will have on its consolidated financial statements.

In January 2017 , the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business* . Public companies should apply these amendments to annual periods beginning after December 15, 2017, including interim periods within those periods. All other entities should apply the amendments to annual periods beginning after December 15, 2018, and interim periods within annual periods beginning after December 15, 2019. The Company is currently evaluating the effect that the adoption of ASU 2017-01 will have on its consolidated financial statements.

Note 3—Prepaid Expenses and Other:

The Company, from time to time, makes payments to certain vendors for which the service relates to future periods. In these cases, the Company classifies these expenses as prepaid and other and amortizes those payments over the period for which the services relate. In some cases, the vendors require an upfront payment to be applied to the final invoices under the agreements. In those cases, if the contract extends beyond the period of one year, the prepayments are classified as long-term. Prepaid expenses and other consisted of the following (in thousands):

	September 30, 2017	December 31, 2016
Current:		
CRO services	$ 6,724	$ 3,471
Other clinical development	664	1,069
Insurance	255	1,159
Other	1,638	1,299
	9,281	6,998
Long-term:		
CRO services	1,726	5,077
Other clinical development	565	1,243
Insurance	16	40
Other	1,544	486
	3,851	6,846
Totals	$ 13,132	$ 13,844

Note 4—Property and Equipment:

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

Property and Equipment:	September 30, 2017	December 31, 2016
Leasehold improvements	$ 3,878	$ 3,878
Computer equipment	2,112	1,822
Telephone equipment	296	256
Furniture and fixtures	2,207	2,146
	8,493	8,102
Less: accumulated depreciation and amortization	(3,779)	(2,949)
Totals	$ 4,714	$ 5,153

Note 5—Intangible assets, net:

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

	September 30, 2017	Estimated useful life
Acquired and in-licensed rights	$ 50,000	13 Years
Less: accumulated amortization	(621)	
Total intangible asset, net	$ 49,379	

Note 6—Accrued Expenses:

Accrued expenses consisted of the following (in thousands):

	September 30, 2017	December 31, 2016
Accrued CRO services	$ 8,323	$ 6,609
Accrued other clinical development	7,243	7,015
Accrued legal fees	2,806	706
Accrued compensation	8,486	3,058
Accrued in-licensed rights	50,000	—
Other	2,750	38
Totals	$ 79,608	$ 17,426

Accrued CRO services represent the Company's estimate of such costs and will be adjusted in the period the actual costs become known. Accrued compensation includes estimated bonus and earned but unused vacation for full-time employees. When actual performance bonuses are paid out to employees, the bonus expense will be adjusted to reflect the actual expense for the year. Accrued in-licensed rights represent amounts owed pursuant to the Company's license agreement with the Licensor. Pursuant to the license agreement, the Company licensed certain intellectual property rights for neratinib and is obligated to make a one-time regulatory milestone payment to the Licensor upon obtaining regulatory approval of its NDA from the FDA. Additionally, vacation is accrued at the rate the employee earns vacation and reduced as vacation is used by the employee.

Note 7—Stockholders' Equity:

Stock-Based Compensation:

The Company's 2011 Plan was adopted by the board of directors on September 15, 2011. Pursuant to the 2011 Plan, the Company may grant incentive stock options, nonqualified stock options and restricted stock units, 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 and restricted stock units 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, 2017, a total of 12,529,412 shares of the Company's common stock have been reserved for issuance under the 2011 Plan.

The Company's 2017 Employment Inducement Incentive Award Plan, or the 2017 Plan, was adopted by the board of directors on April 27, 2017. Pursuant to the 2017 Plan, the Company may grant stock options and restricted stock units, as well as other forms of equity-based compensation to employees, as an inducement to join the Company. The maximum term of stock options granted under the 2017 Plan is 10 years. The exercise price of stock options granted under the 2017 Plan must be at least equal to the fair market value of such shares on the date of grant. As of September 30, 2017, 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, 2017, 233,250 shares have been awarded under the 2017 Plan.

Employee stock-based compensation for the three and nine months ended September 30, 2017 and 2016 were as follows (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Stock-based compensation:				
Options -				
Research and development, or R&D	$ 15,825	$ 20,258	$ 54,062	$ 66,376
Selling, general and administrative, or SG&A	5,817	6,802	18,371	18,852
Performance shares - R&D	—	68	—	139
Restricted stock units -				
R&D	2,333	1,754	6,185	1,754
SG&A	2,513	869	4,595	869
Total stock-based compensation expense	$ 26,488	$ 29,751	$ 83,213	$ 87,990

Stock Options and Restricted Stock Units:

The fair value of options granted to employees was estimated using the Black-Scholes Option Pricing Method (see Note 2—Significant Accounting Policies) with the following weighted-average assumptions used during the nine months ended September 30, 2017 and 2016:

	2017	2016
Dividend yield	0.0%	0.0%
Expected volatility	70.2%	67.3%
Risk-free interest rate	2.0%	1.4%
Expected life in years	5.83	5.72

Activity with respect to options granted under the 2011 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, 2016	6,578,522	$ 87.52	8.0	$ 18,442
Granted	519,791	$ 38.87		
Forfeited	(272,399)	$ 50.26		
Exercised	(419,504)	$ 46.85		$ 18,366
Expired	(111,218)	$ 117.89		
Outstanding at September 30, 2017	6,295,192	$ 87.29	7.4	$ 318,349
Nonvested at September 30, 2017	2,333,232	58.97	8.8	$ 151,369

At September 30, 2017, total estimated unrecognized employee compensation cost related to nonvested stock options and restricted stock units granted prior to that date were approximately $68.7 million and $56.3 million, respectively. These unrecognized expenses are expected to be recognized over a weighted-average period of 1.4 years for stock options and 2.5 years for restricted stock units. The weighted-average grant date fair value of options granted during the nine months ended September 30, 2017 and 2016, were $24.30 per share and $26.79 per share, respectively.

Stock options	Shares	Weighted Average Grant-Date Fair Value
Nonvested shares at December 31, 2016	3,106,083	$ 47.78
Granted	519,791	24.30
Vested/Issued	(1,020,243)	61.53
Forfeited	(272,399)	30.28
Nonvested shares at September 30, 2017	2,333,232	35.31

Restricted stock units have been awarded to certain employees under the 2011 and 2017 Plan. These awards vest over three years.

Restricted stock units	Shares	Weighted Average Grant-Date Fair Value
Nonvested shares at December 31, 2016	630,508	$ 54.35
Granted	569,750	79.82
Vested/Issued	(203,892)	54.35
Forfeited	(40,306)	54.35
Nonvested shares at September 30, 2017	956,060	$ 69.53

Note 8—401(k) Savings Plan:

During 2012, the Company adopted a 401(k) savings plan for the benefit of its employees. The Company is required to make matching contributions to the 401(k) plan equal to 100% of the first 3% of wages deferred by each participating employee and 50% on the next 2% of wages deferred by each participating employee. The Company incurred expenses for employer matching contributions of approximately $0.6 million and $0.7 million for the nine months ended September 30, 2017 and 2016, respectively.

Note 9—Commitments and Contingencies:

Legal Matters

The Company is involved in various lawsuits, claims and other legal matters from time to time that arise in the ordinary course of conducting business. The Company records a liability when a particular contingency is probable and estimable. The Company has not accrued for any contingency at September 30, 2017, as the Company does not consider any contingency to be probable or estimable. The Company faces contingencies that are reasonably possible to occur; however, they cannot currently be estimated. While complete assurance cannot be given to the outcome of these proceedings, management does not currently believe that any of these matters, individually or in the aggregate, will have a material adverse effect on the Company's financial condition, liquidity or results of operations.

Legal Proceedings

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

On June 3, 2015, Hsingching Hsu or the "plaintiff," individually and on behalf of all others similarly situated, filed a class action lawsuit against us or "the defendants" and certain of our executive officers in the United States District Court for the Central District of California (Case No. 8:15-cv-00865-AG-JCG). On October 16, 2015, lead plaintiff Norfolk Pension Fund filed a consolidated complaint on behalf of all persons who purchased our securities between July 22, 2014 and May 29, 2015. The consolidated complaint alleges that the Company and certain of our executive officers made false or misleading statements and failed to disclose material adverse facts about our business, operations, prospects and performance in violation of Sections 10(b) (and Rule 10b-5 promulgated thereunder) and 20(a) of the Exchange Act. The plaintiff seeks damages, interest, costs, attorneys' fees, and other unspecified equitable relief. On September 30, 2016, the court denied the defendants' motion to dismiss the consolidated complaint.

On June 6, 2017, the lead plaint iff filed a first amended complaint that included new claims about additional statements that plaintiff alleges are false or misleading. On June 19, 2017, defendants moved to dismiss the new claims in the amended complaint. On July 25, 2017, the court de nied the motion to dismiss. A trial date is currently set for November 6, 2018. The Company intends to vigorously defend against this matter.

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

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

Derivative Actions

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

Stockholder Demand

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

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

Royalty Payments

Under the Company's license agreement with the Licensor, pursuant to which the Company licensed certain intellectual property rights for neratinib, the Company is obligated to make a one-time regulatory milestone payment to the Licensor upon obtaining regulatory approval of its NDA from the FDA. The Company is also required to make royalty payments on net product sales, if any.

Note 10—Subsequent Events:

The Company entered into a loan agreement with Silicon Valley Bank and Oxford Finance for a term loan of up to $100.0 million, subject to funding in two tranches. The Company received gross proceeds of $50.0 million from the first tranche of the credit facility upon closing on October 31, 2017 and intends to use the funds for general corporate purposes and to further support NERLYNX commercial initiatives. The second tranche of $50.0 million may be drawn at the Company's option between March 31, 2018 and June 30, 2018 provided the Company has achieved a specified minimum revenue milestone and no event of default is occurring. The loan will mature on October 31, 2022.

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, 2016.

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

Overview

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

We submitted a New Drug Application, or NDA, with the U.S. Food and Drug Administration, or FDA for regulatory approval of neratinib in the extended adjuvant setting in the United States in July 2016 and a Marketing Authorization Application, or MAA, with the European Medicines Agency, or EMA, in June 2016. On July 17, 2017, we received regulatory approval of our first product, NERLYNX (neratinib), formally known as PB272 (neratinib (oral)), for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer following adjuvant trastuzumab-based therapy from the FDA. We must receive equivalent foreign regulatory approval to begin selling a drug product in countries other than the United States. We recently commenced commercialization of NERLYNX in the United States using a direct sales force and are continuing to evaluate potential commercialization options for neratinib in this indication outside the United States, if approved, including developing a direct sales force, contracting with third parties to provide sales and marketing capabilities, some combination of these two options or other strategic options. We expect that our expenses will continue to increase as we continue commercialization efforts.

Critical Accounting Policies

As of the date of the filing of this Quarterly Report, we believe there have been no material changes to our critical accounting policies and estimates during the nine months ended September 30, 2017 from our accounting policies at December 31, 2016, as reported in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, with the exception of those listed below.

Accounts Receivable:

Accounts receivable are recorded net of customer allowances for distribution fees, prompt payment discounts, chargebacks, and doubtful accounts. Allowances for distribution fees, prompt payment discounts and chargebacks are based on contractual terms. The Company estimates the allowance for doubtful accounts based on existing contractual payment terms, actual payment patterns of its customers and individual customer circumstances. At September 30, 2017, the Company determined that an allowance for doubtful accounts was not required. No accounts were written off during the periods presented.

License Fees and Royalties:

We expense 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. We have determined that technological feasibility for our product candidates is reached when the requisite regulatory approvals are obtained to make the product available for sale.

In connection with the FDA approval of NERLYNX in July 2017, we triggered a one-time milestone payment pursuant to our 2014 license agreement with the Pfizer, Inc., or Pfizer or the Licensor. We capitalized the milestone payment as an intangible asset

and are amortizing the asset on a straight-line basis over the estimated useful life of the licensed patent through 2030. We recorded amortization expense related to our intangible asset of $0. 6 million for the three months ended September 30, 20 17. As of September 30, 2017, estimated future amortization expense related to our intangible asset was $1.0 million for the remainder of 2017, approximately $3.9 million for each year starting 2018 through 2029, and $1.0 million for 2030.

Royalties incurred in connection with the license agreement with the Licensor, as disclosed in Note 9, are expensed to cost of sales as sales from product revenue is recognized.

Intangible Assets:

We maintain definite-lived intangible assets related to the Licensor agreement. 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.

We assess our 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 negative additional clinical or nonclinical data regarding one of our drug candidates or a potentially competitive drug candidate, adverse changes in the clinical development program for a drug candidate, or new information regarding potential sales for the drug. If impairment indicators are present or changes in circumstance suggest that impairment may exist, we perform a recoverability test by comparing the sum of the estimated undiscounted cash flows of each intangible asset to its carrying value on the condensed consolidated balance sheet. If the undiscounted cash flows used in the recoverability test are less than the carrying value, we 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.

Inventory:

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

We capitalize inventory costs associated with our products after regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. Inventory acquired prior to receipt of marketing approval of a product candidate is expensed as research and development expense as incurred. Inventory that can be used in either the production of clinical or commercial product is expensed as research and development expense when selected for use in a clinical trial. Starter kits, provided to patients prior to insurance approval, are expensed by us to sales and marketing expense as incurred.

Revenue Recognition:

We adopted Accounting Standards Codification ("ASC") Topic 606 - Revenue from Contracts with Customers ("Topic 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 Topic 606, an entity recognizes revenue when its customer obtains control of the promised goods or services, in an amount that reflects the consideration which the entity expects to be entitled in exchange for those goods or services. We had no contracts with customers until the FDA approved NERLYNX on July 17, 2017. Subsequent to receiving FDA approval, we entered into a limited number of arrangements with specialty pharmacies ("SPs") and specialty distributors ("SDs") in the U.S. (collectively, its "Customers") to distribute NERLYNX. These arrangements are our initial contracts with customers. We have determined that these sales channels with our customers are similar.

To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only apply the five-step model to arrangements that meet the definition of a contract under Topic 606, including when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the

scope of Topic 606, we assess the goods or services promised within each contract and determine those that are performance obligations, a nd assesses whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product Revenue:

We sell NERLYNX to a limited number of customers in the U.S. These customers subsequently resell our products to patients and certain medical centers or hospitals. In addition to distribution agreements with Customers, we enter 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 our products. Our payment terms range between 10 and 60 days.

We recognize revenue on product sales when the customer obtains control of our product, which occurs at a point in time (upon delivery). Product revenue is recorded net of applicable reserves for variable consideration.

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

If taxes should be collected from customers relating to product sales and remitted to governmental authorities, they will be excluded from revenue. We expense incremental costs of obtaining a contract when incurred, if the expected amortization period of the asset that we would have recognized is one year or less. However, no such costs were incurred during the three months ended September 30, 2017.

Reserves for Variable Consideration:

Product revenue is recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established. Components of variable consideration include trade discounts and allowances, product returns, provider chargebacks and discounts, government rebates, payor rebates, and other incentives, such as voluntary patient assistance, and other allowances that are offered within contracts between us and our customers, payors, and other indirect customers relating to the sale of our products. These reserves, as detailed below, are based on the amounts earned, or to be claimed on the related sales, and are classified as reductions of accounts receivable (if the amount is payable to the customer) or a current liability (if the amount is payable to a party other than a customer). These estimates take into consideration a range of possible outcomes which are probability-weighted in accordance with the expected value method in 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 we are entitled based on the terms of the respective underlying contracts.

The amount of variable consideration which is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. Our analysis also contemplated application of the constraint in accordance with the guidance, under which we determined a material reversal of revenue would not occur in a future period for the estimates detailed below as of September 30, 2017 and, therefore, the transaction price was not reduced further during the three months ended September 30, 2017. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Trade Discounts and Allowances:

We generally provide customers with discounts that include incentive fees that are explicitly stated in our contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized. In addition, we compensate (through trade discounts and allowances) our customers for sales order management, data, and distribution services. However, we have determined such services received to date are not distinct from the sale of our products to the customer and, therefore, these payments have been recorded as a reduction of revenue within the statement of operations and comprehensive loss through September 30, 2017, as well as a reduction to trade receivables, net on the condensed consolidated balance sheets.

Product Returns:

Consistent with industry practice, we offer the customers limited product return rights for damages and expiring product, provided it is within a specified period around the product expiration date as set forth in the applicable individual distribution agreement. We estimate the amount of our product sales that may be returned by our customers and record this estimate as a reduction

of revenue in the period the related product revenue is recognized, as well as reductions to trade receivables, net on the condensed conso lidated balance sheets. We currently estimate product return liabilities using available industry data and our own sales information, including our visibility into the inventory remaining in the distribution channel. We have not received any returns to dat e and believe that future returns of our products will 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 customers who directly purchase the product from us. Customers charge us for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and trade receivables, net on the condensed consolidated balance sheets. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider by customers, and we generally issue credits for such amounts within a few weeks of the customer's notification to us of the resale. Reserves for chargebacks consist of credits that we expect to issue for units that remain in the distribution channel inventories at each reporting period-end that we expect will be sold to qualified healthcare providers, and chargebacks that customers have claimed, but for which we have not yet issued a credit.

Government Rebates:

We are subject to discount obligations under state Medicaid programs and Medicare. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability, which is included in accrued expenses and other current liabilities on the condensed consolidated balance sheets. For Medicare, we also estimate the number of patients in the prescription drug coverage gap for whom we will owe an additional liability under the Medicare Part D program. Our liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel inventories at the end of each reporting period.

Payor Rebates:

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

Other Incentives:

Other incentives that we offer 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 we expect to receive associated with product that has been recognized as revenue, but remains in the distribution channel inventories 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 condensed consolidated balance sheets.

Components of Results of Operations

Product Revenue, Net:

Product revenue, net consist of sales of NERLYNX, our first and only commercial product to date. The FDA approved NERLYNX in July 2017, and we launched the product in the United States in September 2017.

Operating Expenses

Cost of sales consists of third-party manufacturing costs, freight, royalties, and indirect overhead costs associated with sales of NERLYNX. Cost of sales may also include period costs related to certain inventory manufacturing services, inventory adjustment charges, unabsorbed manufacturing and overhead costs, and manufacturing variances. The cost of manufacturing NERLYNX prior to FDA approval in July 2017 has been expensed. Due to that, the cost of sales will appear artificially low until additional product is manufactured.

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, pre paration for commercialization and other corporate expenses.

Research and development, or R&D, expenses include costs associated with services provided by consultants who conduct clinical services on our behalf, contract organizations for manufacturing of clinical materials and clinical trials. During the nine months ended September 30, 2017 and 2016, 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.

Results of Operations

Three Months Ended September 30, 2017 Compared to Three Months Ended September 30, 2016

Product revenue, net

Product revenue, net was $6.1 million for the three months ended September 30, 2017 compared to $0 for the three months ended September 30, 2016. The increase in product revenue, net was entirely attributable to the commercial launch of NERLYNX, our initial product, in July 2017.

Cost of sales

Cost of sales was $1.5 million for the three months ended September 30, 2017 compared to $0 for the three months ended September 30, 2017. The increase in cost of sales was entirely attributable to the commercial launch of NERLYNX, our initial product, in July 2017.

Selling, general and administrative expenses:

For the three months ended September 30, 2017, SG&A expenses were approximately $32.5 million, compared to approximately $14.0 million for the three months ended September 30, 2016. SG&A expenses for the three months ended September 30, 2017 and 2016 were as follows:

Selling, general and administrative expenses (in thousands)	For the Three Months Ended September 30, 2017	2016	Period to period percentage change
Professional fees and expenses	$ 13,124	$ 2,644	396.4%
Payroll and related costs	7,804	1,680	364.5%
Facility and equipment costs	1,249	1,251	(0.2%)
Employee stock-based compensation expense	8,330	7,671	8.6%
Other	1,982	776	155.4%
	$ 32,489	$ 14,022	131.7%

For the three months ended September 30, 2017, SG&A expenses increased approximately $18.5 million compared to the same period in 2016. Approximately $0.7 million of the increase was related to an increase in stock-based compensation expense attributable to our increased headcount and additional incentive awards to existing employees. The remaining $17.8 million of the increase in SG&A expense for the three months ended September 30, 2017, compared to the same period in 2016, was primarily attributable to:

- an approximately $10.5 million increase in professional fees and expenses, which consist primarily of commercial systems implementation costs, recruiting and consulting fees for the hiring of the salesforce and supporting positions, and legal, auditing, and investor relations fees. We expect these fees to continue at similar levels during the remainder of 2017 as we continue to use consultants to commercialize NERLYNX in the U.S. market, defend against the class action, derivative and defamation lawsuits filed against us, and as we support compliance measures related to the Sarbanes Oxley Act of 2002, as amended, or Sarbanes Oxley, and various healthcare compliance measures.
- an approximately $6.1 million increase in payroll and related costs, as administrative headcount increased from 23 to 153, primarily in sales and marketing functions to commercially launch NERLYNX and to support corporate growth. We expect these payroll and related costs to continue to increase slightly as we hire additional sales force personnel and supporting staff in the third and fourth quarter of 2017.

- an approximately $1.2 million increase in other expenses primarily attributable to increased travel and travel related expenses for the commercial launch of NERLYNX and increased consulting costs related to the commercial launch.

Research and development expenses:

For the three months ended September 30, 2017, R&D expenses were approximately $49.5 million, compared to approximately $52.0 million for the three months ended September 30, 2016. R&D expenses for the three months ended September 30, 2017 and 2016 were as follows:

Research and development expenses (in thousands)	For the Three Months Ended September 30, 2017	2016	Period to period percentage change
Clinical trial expense	$ 16,557	$ 17,889	(7.4%)
Internal clinical development	7,366	6,179	19.2%
Consultants and contractors	4,258	2,973	43.2%
Internal regulatory affairs and quality assurance	2,585	2,361	9.5%
Internal chemical manufacturing	578	495	16.8%
Employee stock-based compensation	18,158	22,080	(17.8%)
	$ 49,502	$ 51,977	(4.8%)

For the three months ended September 30, 2017, R&D expenses decreased approximately $2.5 million compared to the same period in 2016. Stock-based compensation expense decreased approximately $3.9 million, and consists of forfeitures for employees who exited the company, offset by grants to new employees and additional awards to existing employees for the three months ended September 30, 2017. Further to this decrease was a decrease in clinical trial expense of approximately $1.3 million primarily attributable to decreased expenses for preclinical studies and drug supply manufacturing logistics. The decreases in expenses were partially offset by:

- a slight increase of approximately $1.5 million in internal clinical development, internal regulatory affairs and quality assurance, and internal chemical manufacturing expenses due to wage progression and a slight increase in headcount to 155 from 135 for the three months ended September 30, 2017, compared to the same period in 2016.
- an approximately $1.3 million increase in consultants and contractors related expenses due to increased consulting in program management to support medical affairs and compliance, and additional consulting expense for clinical trial site monitoring as enrollment increased in an ongoing clinical trial.

We expect R&D expenses, excluding stock-based compensation, to continue at levels similar to the three months ended September 30, 2017, for our existing clinical trials as we conclude the work performed by CRO and related clinical services; however, should we choose to pursue additional clinical trials, R&D expenses may increase accordingly.

Nine Months Ended September 30, 2017 Compared to Nine Months Ended September 30, 2016

Product revenue, net

Product revenue, net was $6.1 million for the nine months ended September 30, 2017 compared to $0 for the nine months ended September 30, 2016. The increase in product revenue, net was entirely attributable to the commercial launch of NERLYNX, our initial product, in July 2017.

Cost of sales

Cost of sales was $1.5 million for the nine months ended September 30, 2017 compared to $0 for the nine months ended September 30, 2017. The increase in cost of sales was entirely attributable to the commercial launch of NERLYNX, our initial product, in July 2017.

Selling, general and administrative expenses:

For the nine months ended September 30, 2017, SG&A expenses were approximately $75.8 million, compared to approximately $37.3 million for the nine months ended September 30, 2016. SG&A expenses for the nine months ended September 30, 2017 and 2016 were as follows:

Selling, general and administrative expenses (in thousands)	For the Nine Months Ended September 30, 2017	2016	Period to period percentage change
Professional fees and expenses	$ 31,442	$ 7,242	334.2%
Payroll and related costs	13,068	4,870	168.3%
Facility and equipment costs	3,741	3,313	12.9%
Employee stock-based compensation expense	22,966	19,721	16.5%
Other	4,602	2,180	111.1%
	$ 75,819	$ 37,326	103.1%

For the nine months ended September 30, 2017, SG&A expenses increased approximately $38.5 million compared to the same period in 2016. Approximately $3.2 million of the increase was related to an increase in stock-based compensation expense attributable to our increased headcount and additional incentive awards to existing employees. The remaining $35.2 million of the increase in SG&A expense for the nine months ended September 30, 2017, compared to the same period in 2016, was primarily attributable to:

- an approximately $24.2 million increase in professional fees and expenses, which consist primarily of commercial systems implementation costs, recruiting and consulting fees for the hiring of the salesforce and supporting positions, and legal, auditing, and investor relations fees.
- an approximately $8.2 million increase in payroll and related costs as administrative headcount increased from 23 to 153 primarily in sales and marketing functions to support corporate growth and to prepare for the commercial launch of NERLYNX.
- an approximately $0.4 million increase in facility and equipment costs due to additional office space leased beginning April 2016.
- An increase of approximately $2.4 million in other expenses primarily due to an increase of approximately $1.1 million for travel and travel related expenses to support the commercial launch of NERLYNX and approximately $0.4 million of consulting costs related to commercializing NERLYNX.

Research and development expenses:

For the nine months ended September 30, 2017, R&D expenses were approximately $157.6 million, compared to approximately $166.4 million for the nine months ended September 30, 2016. R&D expenses for the nine months ended September 30, 2017 and 2016 were as follows:

Research and development expenses (in thousands)	For the Nine Months Ended September 30, 2017	2016	Period to period percentage change
Clinical trial expense	$ 55,372	$ 60,342	(8.2%)
Internal clinical development	21,620	19,576	10.4%
Consultants and contractors	11,206	9,217	21.6%
Internal regulatory affairs and quality assurance	7,407	7,542	(1.8%)
Internal chemical manufacturing	1,704	1,454	17.2%
Employee stock-based compensation	60,247	68,269	(11.8%)
	$ 157,556	$ 166,400	(5.3%)

For the nine months ended September 30, 2017, R&D expenses decreased approximately $8.8 million compared to the same period in 2016. Stock-based compensation expense decreased approximately $8.0 million, which consisted of forfeitures for employees who exited the company, offset by grants to new employees and additional awards to existing employees for the nine months ended September 30, 2017. Further to this decrease was a decrease in clinical trial expense of approximately $5.0 million

primarily attributable to decreased expenses due to a decrease in regulatory submission activity during the nine months ended September 30, 2017 compared to the same period in 2016, decreased preclinical study activities and decreased drug supp ly manufacturing logistics. The decreases in expenses were offset by:

- an increase of approximately $2.2 million in internal clinical development, internal regulatory affairs and quality assurance, and internal chemical manufacturing expenses due to wage progression along with a slight increase in headcount to 155 from 135 for the nine months ended September 30, 2017, compared to the same period in 2016.
- an approximately $2.0 million increase in consultants and contractors related expenses due to increased consulting in support of program management to support medical affairs and compliance, and additional consulting expense for clinical trial site monitoring as enrollment increased in an ongoing clinical trial.

While expenditures on current and future clinical development programs, particularly our PB272 program, are expected to be substantial, they are subject to many uncertainties, including the results of clinical trials and whether we develop any of our drug candidates with a partner or independently. As a result of such uncertainties, we cannot predict with any significant degree of certainty the duration and completion costs of our research and development projects or whether, when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates. The duration and cost of clinical trials may vary significantly over the life of a project as a result of unanticipated events arising during clinical development and a variety of other factors, including:

- the number of trials and studies in a clinical program;
- the number of patients who participate in the trials;
- the number of sites included in the trials;
- the rates of patient recruitment and enrollment;
- the duration of patient treatment and follow-up;
- the costs of manufacturing our drug candidates; and
- the costs, requirements, timing of, and ability to secure regulatory approvals.

Interest income:

For the three and nine months ended September 30, 2017, we recognized approximately $0.3 million and $1.0 million in interest income, compared to approximately $0.2 million and $0.8 million for the same periods in 2016, respectively. The increase in interest income is due to the additional cash, cash equivalents and marketable securities on hand for the three and nine months ended September 30, 2017, from the underwritten public offering in October 2016.

Other expenses:

During the three and nine months ended September 30, 2017, other expenses, consisting primarily of foreign exchange loss, were approximately $0.0 and $0.1 million. During the same periods in 2016, other expenses were approximately $$0.0 and $0.4 million. The nine months ended September 30, 2016 included approximately $0.4 million on the disposal of leasehold improvements due to the relocation of our South San Francisco office.

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of September 30, 2017 and December 31, 2016, and for the nine months ended September 30, 2017 and 2016, and is intended to supplement the more detailed discussion that follows:

Liquidity and capital resources (in thousands)	September 30, 2017	December 31, 2016
Cash and cash equivalents	$ 79,717	$ 194,494
Marketable securities	26,620	34,982
Working capital	22,345	199,013
Stockholders' equity	79,168	209,824

	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016
Cash provided by (used in):		
Operating activities	$ (136,861)	$ (100,729)
Investing activities	8,082	121,350
Financing activities	14,002	351
(Decrease) increase in cash and cash equivalents	$ (114,777)	$ 20,972

Operating Activities:

For the three and nine months ended September 30, 2017, we reported a net loss of approximately $77.2 million and $227.9 million, compared to approximately $65.8 million and $203.4 million for the same periods in 2016, respectively. Additionally, cash used in operating activities for the three and nine months ended September 30, 2017 was approximately $54.9 million and $136.9 million, respectively, compared to approximately $34.9 million and $100.7 million for the same periods in 2016, respectively.

Cash used in operating activities for the nine months ended September 30, 2017 consisted of a net loss of $227.9 million, offset by approximately $84.7 million of non-cash items such as depreciation and amortization and stock-based compensation, an increase of approximately $3.9 million in accounts receivables, an increase of approximately $0.1 million for inventory, an increase of approximately $9.7 million in accrued expenses and accounts payable, a decrease of approximately $0.1 million for deferred rent and a decrease of approximately $0.7 million in prepaid expenses and other.

Cash used in operating activities for the nine months ended September 30, 2016 consisted of a net loss of $203.4 million, offset by approximately $91.9 million of non-cash items such as depreciation and amortization, a build-out allowance from the landlord for our office space, the disposal of leasehold improvements and stock-based compensation; an increase of approximately $3.9 million in the liability for deferred rent; an increase in other receivables of approximately $1.2 million related to the build-out allowance to be received from the landlord; an increase of approximately $5.2 million in accrued expenses and accounts payable; and a decrease in prepaid expenses and other of approximately $2.8 million

Investing Activities:

During the nine months ended September 30, 2017, net cash provided by investing activities was approximately $8.1 million, compared to approximately $121.4 million for the same period in 2016. The approximately $8.1 million of net cash provided by investing activities during the nine months ended September 30, 2017 was made up of approximately $88.1 million of sales or maturities of available-for-sale securities, offset by $79.7 million of cash invested in available-for-sale securities, and approximately $0.3 million used to purchase property and equipment. During the nine months ended September 30, 2016, cash provided by investing activities was primarily made up of approximately $81.8 million used for the purchase of available-for-sale securities, offset by approximately $209.9 million of cash provided by the sale or maturities of available-for-sale securities, approximately $3.7 million used to purchase property and equipment and approximately $3.0 million of expenditures for leasehold improvements.

Financing Activities:

During the nine months ended September 30, 2017, cash provided by financing activities consisted of approximately $14.0 million of net proceeds from the exercise of stock options. During the same period in 2016, cash provided by financing activities was approximately $0.4 million, also comprised of net proceeds from the exercise of stock options.

Current and Future Financing Needs:

We have incurred negative cash flows from operations since we started our business. On July 17, 2017, we received FDA approval of our first product, NERLYNX. NERLYNX is now commercially available by prescription in the United States and we received our first product revenue during the three months ending September 30, 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 continuing commercialization efforts. Given the current and desired pace of clinical development of our product candidates, over the next 12 months we estimate that our R&D spending will be approximately $130 million to $145 million, excluding stock-based compensation. Furthermore, the FDA approval of the NDA triggered a milestone payment due to the Licensor. Additionally, we expect increased SG&A expenses as we continue to commercialize NERLYNX.

Ongoing commercialization may require funding in addition to the cash and cash equivalents and marketable securities totaling approximately $106.3 million available at September 30, 2017. While our unaudited 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 based on the approval by the FDA for the United States and, if approved, by the EMA, launch in the European Union. While we have been successful in raising financing in the past, there can be no assurance that we will be able to do so in the future. Our ability to obtain funding may be adversely impacted by uncertain market conditions, unfavorable decisions of regulatory authorities or adverse clinical trial results. The outcome of these matters cannot be predicted at this time.

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

Credit Facility

On October 31, 2017, we entered into a loan and security agreement, which we refer to as the credit facility, with Silicon Valley Bank, or SVB, as administrative and collateral agent, and the lenders party thereto from time to time, including Oxford Finance LLC, or Oxford, and SVB, pursuant to which the lenders agreed to make term loans available to us in an aggregate amount of $100 million, consisting of (i) a Term Loan A in an aggregate amount of $50 million available on the effective date and (ii) a Term Loan B in an aggregate amount of $50 million available to be drawn at our option between March 31, 2018 and June 30, 2018 provided we have achieved a specified minimum revenue milestone and no event of default is occurring. Proceeds from the Term Loans may be used for working capital and general business purposes. Upon the entry into the credit facility, we were required to pay the lenders aggregate fees of $1,500,000, consisting of a facility fee of $750,000 and an arrangement fee of $750,000. The credit facility is secured by substantially all of our personal property other than our intellectual property. We also pledged 65% of the issued and outstanding capital stock of our subsidiary, Puma Biotechnology Ltd. The credit facility limits our ability to grant any interest in our intellectual property to certain permitted licenses and permitted encumbrances set forth in the agreement.

The Term Loans under the credit facility bear interest at an annual rate equal to the greater of (i) 7.75% and (ii) the sum of (a) the "prime rate," as reported in The Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 3.5%. We are required to make monthly interest-only payments on each Term Loan commencing on the first calendar day of the calendar month following the funding date of such Term Loan, and continuing on the first calendar day of each calendar month thereafter through December 1, 2019, 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, calculated pursuant to the credit facility. All unpaid principal and accrued and unpaid interest with respect to each Term Loan is due and payable in full on October 31, 2022. Upon repayment of the Term Loans, we are also required to make a final payment to the lenders equal to 7.5% of the original principal amount of Term Loans funded.

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

The credit facility includes affirmative and negative covenants applicable to us, our current subsidiary and any subsidiaries we create in the future. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and satisfy certain requirements regarding deposit accounts. We must also achieve product revenue, measured as of the last day of each fiscal quarter on a trailing 3-month basis, that is (i) greater than or equal to 70% of the revenue target set forth in our board-approved projections for the 2017 fiscal year, (ii) greater than or equal to 50% of the revenue target set forth in our board-approved projections for the 2018 fiscal year, and (iii) greater than or equal to 50% of the revenue target set forth in our board-approved projections for the 2019 fiscal year. New minimum revenue levels will be established for each subsequent fiscal year by mutual agreement of us, SVB, as administrative agent, and the lenders. The negative covenants include, among others, restrictions on us transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, creating liens, selling assets and suffering a change in control, in each case subject to certain exceptions.

The credit facility also includes events of default, the occurrence and continuation of which could cause interest to be charged at the rate that is otherwise applicable plus 5.0% and would provide SVB, as collateral agent, with the right to exercise remedies against us and the collateral securing the credit facility, including foreclosure against the property securing the credit facilities, including our cash. These events of default include, among other things, our failure to pay principal or interest due under the credit facility, a breach of certain covenants under the credit facility, our insolvency, a material adverse change, the occurrence of any default under certain other indebtedness in an amount greater than $500,000 and one or more judgments against us in an amount greater than $500,000 individually or in the aggregate.

Going Concern

Our former independent registered public accounting firm issued a report on our audited consolidated financial statements for the year ended December 31, 2016 that included an explanatory paragraph referring to our significant operating losses and expressing substantial doubt in our ability to continue as a going concern. Our unaudited condensed consolidated financial statements have been prepared on a going concern basis, which assumes the realization of assets and settlement of liabilities in the normal course of business. Our ability to continue as a going concern is dependent upon our ability to generate profitable operations in the future or to obtain the necessary financing to meet our obligations and repay our liabilities arising from normal business operations when they become due. The outcome of these matters cannot be predicted with any certainty at this time and raise substantial doubt that we will be able to continue as a going concern. Our consolidated financial statements do not include any adjustments to the amount and classification of assets and liabilities that may be necessary should we be unable to continue as a going concern.

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 employee stock-based compensation. Stock-based compensation represented approximately 34.3% and 36.5% of our net loss for the three and nine months ended September 30, 2017, respectively, and approximately 45.2% and 43.3% for the same periods in 2016. Although net loss is important to measure our financial performance, we currently place an emphasis on cash burn and, more specifically, cash used in operations. Because stock-based compensation appears in the GAAP net loss but is removed from net loss to arrive at cash used in operations on the statement of cash flows due to its non-cash nature, we believe these non-GAAP measures enhance understanding of our financial performance, are more indicative of our operational performance and facilitate a better comparison among fiscal periods. These non-GAAP financial measures are not, and should not be viewed as, substitutes for GAAP reporting measures.

Reconciliation of GAAP Net Loss to Non-GAAP Adjusted Net Loss and GAAP Net Loss Per Share to Non-GAAP Adjusted Net Loss Per Share

(in thousands except share and per share data)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,		
	2017	2016	2017	2016	
GAAP net loss	$ (77,180)	$ (65,781)	$ (227,877)	$ (203,350)	
Adjustments:					
Stock-based compensation -					
Selling, general and administrative	8,330	7,671	22,966	19,721	(1)
Research and development	18,158	22,080	60,247	68,269	(2)
Non-GAAP adjusted net loss	$ (50,692)	$ (36,030)	$ (144,664)	$ (115,360)	
GAAP net loss per share ─ basic and diluted	$ (2.07)	$ (2.02)	$ (6.15)	$ (6.26)	
Adjustment to net loss (as detailed above)	0.71	0.91	2.25	2.71	
Non-GAAP adjusted net loss per share	$ (1.36)	$ (1.11)	$ (3.90)	$ (3.55)	(3)

(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 net loss per share was calculated based on 37,214,002 and 32,497,168 weighted average common shares outstanding for the three months ended September 30, 2017 and 2016, respectively, and 37,046,765 and 32,489,584 weighted average common shares outstanding for the nine months ended September 30, 2017 and 2016, respectively.

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

The primary objective of our investing activities is to preserve principal while maximizing the income we receive from our investments without significantly increasing the risk of loss. Some of the investable securities permitted under our cash management policy may be subject to market risk for changes in interest rates. To mitigate this risk, we maintain a portfolio of cash equivalents and available-for-sale investments in a variety of securities, which may include investment grade commercial paper, money market funds, government debt issued by the United States of America, state debt, certificates of deposit and investment grade corporate debt. Presently, we are exposed to minimal market risks associated with interest rate changes because of the relatively short maturities of our investments and we do not expect interest rate fluctuations to materially affect the aggregate value of our financial instruments. We manage our sensitivity to these risks by maintaining investment grade short-term investments. We do not purchase or hold derivative or commodity instruments or other financial instruments for trading purposes. Additionally, we periodically monitor our investments for adverse material holdings related to the underlying financial solvency of the issuer. As of September 30, 2017, our investments consisted primarily of corporate obligations. Our results of operations and financial condition would not be significantly impacted by either a 10% increase or 10% decrease in interest rates, due mainly to the short-term nature of our investment portfolio. We have not used derivative financial instruments in our investment portfolio. Additionally, we do not invest in foreign currencies or other foreign investments.

Item 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures 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 (the

Company’s principal executive officer) and Senior Vice President, Finance and Administration and Treasurer (the Company’s principal finan cial and accounting officer), as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed a nd 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 possib le controls and procedures.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Senior Vice President, Finance and Administration and Treasurer, we have evaluated the effectiveness of our disclosure controls and procedures (as defined under Exchange Act Rule 13a-15(e)), as of September 30, 2017. Based on that evaluation, our Chief Executive Officer and Senior Vice President, Finance and Administration and Treasurer have concluded that these disclosure controls and procedures were effective as of September 30, 2017.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the fiscal quarter ended September 30, 2017, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting other than controls that were added as a result of the Company's commercialization subsequent to FDA approval and the related product launch of NERLYNX.

PART II – OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

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

On June 3, 2015, Hsingching Hsu or the "plaintiff," individually and on behalf of all others similarly situated, filed a class action lawsuit against us or "the defendants" and certain of our executive officers in the United States District Court for the Central District of California (Case No. 8:15-cv-00865-AG-JCG). On October 16, 2015, lead plaintiff Norfolk Pension Fund filed a consolidated complaint on behalf of all persons who purchased our securities between July 22, 2014 and May 29, 2015. The consolidated complaint alleges that we and certain of our executive officers made false or misleading statements and failed to disclose material adverse facts about our business, operations, prospects and performance in violation of Sections 10(b) (and Rule 10b-5 promulgated thereunder) and 20(a) of the Exchange Act. The plaintiff seeks damages, interest, costs, attorneys' fees, and other unspecified equitable relief. On September 30, 2016, the court denied the defendants' motion to dismiss the consolidated complaint. On June 6, 2017, the lead plaintiff filed a first amended complaint that included new claims about additional statements that plaintiff alleges are false or misleading. On June 19, 2017, defendants moved to dismiss the new claims in the amended complaint. On July 25, 2017, the court denied the motion to dismiss. A trial date is currently set for November 6, 2018. We intend to vigorously defend against this matter.

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

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

Derivative Actions

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

Stockholder Demand

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

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

Ite m 1A. RISK FACTORS

In addition to the other information contained in this Quarterly Report, the following risk factors should be considered carefully in evaluating our company. Our business, financial condition, liquidity or results of operations could be materially adversely affected by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us.

Risks Related to our Business

We have a limited operating history and are not profitable and may never become profitable.

We have a limited operating history and until recently our efforts and resources have been focused primarily on acquiring and developing our pharmaceutical technologies, raising capital and recruiting personnel. On July 17, 2017, the FDA approved our first product, NERLYNX, for the extended adjuvant treatment of early stage, HER2-positive breast cancer in the United States and NERLYNX only recently became commercially available in the United States. We have a history of operating losses with net losses of $227.9 million for the nine months ended September 30, 2017 and $276.0 million and $239.3 million for the fiscal years ended December 31, 2016 and 2015, respectively. As of September 30, 2017, we had an accumulated deficit of approximately $1,024.4 million.

Although we received FDA approval of NERLYNX, we expect to incur substantial losses for the foreseeable future and may never become profitable. Moreover, even if we succeed in developing and commercializing one or more of other drug candidates, we may never become profitable. The successful development and commercialization of any drug candidates will require us to perform a variety of functions, including:

- undertaking pre-clinical development and clinical trials;
- hiring additional personnel;
- participating in regulatory approval processes;
- formulating and manufacturing products;
- initiating and conducting sales and marketing activities; and
- implementing additional internal systems and infrastructure.

We will likely need to raise additional capital in order to fund our business and generate significant revenue in order to achieve and maintain profitability. We may not be able to generate this revenue, raise additional capital or achieve profitability in the future. As a result, we expect our losses to continue for the foreseeable future. Accordingly, we cannot assure you that we will achieve profitability in the future or that, if we do become profitable, we will sustain profitability. Our failure to achieve or maintain profitability could negatively impact the value of our common stock.

Our success depends on our ability to successfully commercialize NERLYNX. We are currently a single product company with limited commercial sales experience, which makes it difficult to evaluate our current business, predict our future prospects and forecast our financial performance and growth.

We have invested a significant portion of our efforts and financial resources in the development and commercialization of our lead product, NERLYNX, which was approved by the FDA for the extended adjuvant treatment of early stage, HER2-positive breast cancer in the United States on July 17, 2017, and we expect NERLYNX to constitute the vast majority of our product revenue for the foreseeable future. Our success depends on our ability to effectively commercialize NERLYNX. Successful commercialization of NERLYNX is subject to many risks. We have never, as an organization, launched or commercialized a product, and there is no guarantee that we will be able to do so successfully with NERLYNX for this indication. There are numerous examples of unsuccessful product launches and failures to meet high expectations of market potential, including by pharmaceutical companies with more experience and resources than we have. We are continuing to build our commercial team and hire our U.S. sales force, and therefore, we will need to further develop and train the team and any new hires in order to be prepared to successfully commercialize of NERLYNX. Even if we are successful in building out our commercial team, there are many factors that could cause the commercialization of NERLYNX to be unsuccessful, including a number of factors that are outside our control. The commercial success of NERLYNX depends on the extent to which patients and physicians accept and adopt NERLYNX. For example, if the expected patient population is smaller than we estimate or if physicians are unwilling to prescribe or patients are unwilling to take NERLYNX due to the related side effects, including diarrhea, the commercial potential of NERLYNX will be limited. In addition, we also do not know how physicians, patients and payors will respond to the pricing of NERLYNX. Thus, significant uncertainty remains regarding the commercial potential of NERLYNX. Moreover, our ability to effectively generate product revenue from NERLYNX will depend on our ability to, among other things:

- achieve and maintain compliance with regulatory requirements;
- create market demand for and achieve market acceptance of NERLYNX through our marketing and sales activities and other arrangements established for the promotion of NERLYNX;
- compete with other breast cancer drugs (either in the present or in the future);
- train, deploy and support a qualified sales force;

- secure formulary approvals for NERLYNX at a substantial number of targeted hospitals;
- the ability of our third-party manufacturers to manufacture NERLYNX in sufficient quantities in compliance with requirements of the FDA and similar foreign regulatory agencies, if NERLYNX is approved by such foreign regulatory agencies, and at acceptable quality and pricing levels in order to meet commercial demand;
- the ability of our third-party manufacturers to develop, validate and maintain commercially viable manufacturing processes that are compliant with current Good Manufacturing Practice, or cGMP, regulations;
- implement and maintain agreements with wholesalers, distributors and group purchasing organizations on commercially reasonable terms;
- ensure that our entire supply chain efficiently and consistently delivers NERLYNX to our customers;
- receive adequate levels of coverage and reimbursement for NERLYNX from commercial health plans and governmental health programs;
- our provision of co-pay assistance to help qualified patients with out-of-pocket costs associated with their NERLYNX prescription and/or other programs to ensure patient access to our products;
- our success in educating physicians and patients about the benefits, administration and use of NERLYNX;
- acceptance of NERLYNX as safe and effective by patients and the medical community;
- the nature of publicity related to our product relative to the publicity related to our competitors' products;
- obtain regulatory approvals for additional indications for the use of NERLYNX; and
- maintain and defend our patent protection and regulatory exclusivity for NERLYNX and to comply with our obligations under, and otherwise maintain, our intellectual property license with Pfizer.

Any disruption in our ability to generate product revenue from the sale of NERLYNX will have a material and adverse impact on our results of operations.

We currently have no experience as a company in marketing or distributing pharmaceutical products. If we are unable to expand our marketing capabilities and effectively commercialize NERLYNX, our business, results of operations and financial condition may be materially adversely affected.

Our strategy is to build our sales, marketing and distribution capabilities to successfully commercialize NERLYNX in the United States. While we are continuing to establish our commercial team and hire our U.S. sales force, we do not have any experience commercializing pharmaceutical products as an organization. In order to successfully market NERLYNX, we must continue to build our sales, marketing, managerial, compliance, and related capabilities or make arrangements with third parties to perform these services. If we are unable to establish adequate sales, marketing, and distribution capabilities, whether independently or with third parties, we may not be able to appropriately commercialize NERLYNX and may not become profitable.

Included in our strategy in the United States is the establishment of a direct sales force to commercialize NERLYNX, and we will need to conduct further activities to develop our sales force. These efforts will continue to be expensive and time-consuming, and we cannot be certain that we will be able to successfully develop this capability. NERLYNX is a newly-marketed drug and, therefore, none of the members of our sales force has ever promoted NERLYNX prior to its commercial launch. In addition, we must train our sales force to ensure that a consistent and appropriate message about NERLYNX is being delivered to our potential customers. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits of NERLYNX and its proper administration, our efforts to successfully commercialize NERLYNX could be harmed, which would negatively impact our ability to generate product revenue.

Additionally, even though we have commenced the commercialization of NERLYNX, we will need to maintain and further develop our sales force to achieve commercial success , and we will be competing with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. In the event we are unable to continue to develop and effectively maintain our commercial team, including our U.S. sales force, our ability to successfully commercialize NERLYNX would be limited, and we would not be able to generate product revenue successfully. There are risks involved both with establishing our own sales and marketing capabilities and with ente ring into arrangements with third parties to perform these services. For example, any efforts to develop a direct sales and marketing organization would be subject to numerous risks, including:

- recruiting and training a sales force is expensive and time consuming and could delay any product launch;
- our inability to recruit, retain or motivate adequate numbers of effective and qualified sales and marketing personnel;
- the inability to provide adequate training to sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or convince adequate numbers of physicians to prescribe any future products;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization; and
- the premature or unnecessary incurrence of significant commercialization expenses if the commercial launch of a product is delayed or does not occur for any reason.

Similarly, if we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenue or the profitability associated with any product revenue may be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our proposed products or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. Moreover, we may be negatively impacted by other factors outside of our control relating to such third parties, including, but not limited to, their inability to comply with regulatory requirements. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our proposed products.

We may not be able to secure additional financing on favorable terms, or at all, to meet our future capital needs and our failure to obtain additional financing when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development or commercialization efforts or other operations.

Our operations have consumed substantial amounts of cash since inception. We expect our costs and expenses to increase in the future as we commercialize NERLYNX, including the cost of a direct sales force and the cost of manufacturing. We will also continue to expend substantial amounts on research and development of our other product candidates, including conducting clinical trials. Our future capital requirements will depend on many factors, including:

- the costs and expenses of our U.S. sales and marketing infrastructure;
- the degree of success we experience in commercializing NERLYNX;
- the revenue generated by the sale of NERLYNX and any other products that may be approved in the United States;
- the costs, timing and outcomes of clinical trials and regulatory reviews associated with our other product candidates;
- the emergence of competing products;
- the extent to which NERLYNX is adopted by the physician community and patients;
- the number and types of future products we develop and commercialize;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;
- costs of operating as a public company and compliance with existing and future regulations; and
- the extent and scope of our general and administrative expenses.

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 operation and successfully commercialize NERLYNX. The Company entered into a loan agreement with Silicon Valley Bank and Oxford Finance for a term loan of up to $100.0 million, subject to funding in two tranc hes. The Company received gross proceeds of $50.0 million from the first tranche of the credit facility upon closing on October 31, 2017 and intends to use the funds for general corporate purposes and to further support NERLYNX commercial initiatives. Th e second tranche of $50.0 million may be drawn at the Company's option and subject to the achievement of certain revenue milestones. The loan will mature on October 31, 2022. 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. Additional financing may not be available on a timely basis on terms acceptable to us, or at all. We may raise funds in equity or debt financings to access funds for our capital needs. If we raise ad ditional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution in their percentage ownership of our company, and any new equity securities we issue could have rights, preferenc es and privileges senior to those of holders of our common stock. Any debt financing obtained by us in the future would cause us to incur debt service expenses and could include restrictive covenants relating to our capital raising activities and other fin ancial and operational matters, which may make it more difficult for us to obtain additional capital and pursue business opportunities. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, we may termin ate or delay the development of one or more of our product candidates, delay clinical trials necessary to market our products, or delay establishment of sales and marketing capabilities or other activities necessary to commercialize our products. If this w ere to occur, our ability to continue to grow and support our business and to respond to business challenges could be significantly limited. Furthermore, our ability to obtain funding may be adversely impacted by uncertain market conditions, unfavorable d ecisions of regulatory authorities or adverse clinical trial results. The outcome of these matters cannot be predicted at this time. If the going concern assumption was not appropriate for the preparation of our consolidated financial statements, adjustm ent might be necessary to the consolidated financial statements.

Our former independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

Our historical consolidated financial statements have been prepared under the assumption that we will continue as a going concern. Our former independent registered public accounting firm has issued a report on our audited consolidated financial statements for the year ended December 31, 2016 that included an explanatory paragraph referring to our significant operating losses and expressing substantial doubt in our ability to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity financing or other capital, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue. Our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. However, if adequate funds are not available to us when we need it, we will be required to curtail our operations which would, in turn, further raise substantial doubt about our ability to continue as a going concern. The doubt regarding our potential ability to continue as a going concern may adversely affect our ability to obtain new financing on reasonable terms or at all. Additionally, if we are unable to continue as a going concern, our stockholders may lose some or all of their investment in the Company.

The terms of our credit facility place restrictions on our ability to operate our business and on our financial flexibility, and we may be unable to achieve the revenue necessary for us to incur additional borrowings under the credit facility or to satisfy the minimum revenue covenants.

The terms of our credit facility place restrictions on our ability to operate our business and our financial flexibility. On October 31, 2017, we entered into a loan and security agreement, which we refer to as the credit facility, with Silicon Valley Bank, or SVB, as administrative and collateral agent, and the lenders party thereto from time to time, including SVB and Oxford Finance LLC, or Oxford, pursuant to which the lenders agreed to make term loans available to us in an aggregate amount of $100 million, consisting of (i) a Term Loan A in an aggregate amount of $50 million available on the effective date and (ii) a Term Loan B in an aggregate amount of $50 million available to be drawn at our option between March 31, 2018 and June 30, 2018 provided we have achieved a specified minimum revenue milestone and no event of default is occurring. As of October 31, 2017, we had $50.0 million in principal outstanding under the credit facility. We cannot assure you that we will achieve the revenue milestone that will trigger our ability to draw the Term Loan B, and accordingly, we may never be able to borrow the additional $50.0 million provided for in the credit facility. The credit facility is secured by substantially all of our personal property, other than our intellectual property.

The credit facility includes affirmative and negative covenants applicable to us, our current subsidiary and any subsidiaries we create in the future. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and satisfy certain requirements regarding deposit accounts. We must also achieve product revenue, measured as of the last day of each fiscal quarter on a trailing 3-month basis, that is (i) greater than or equal to 70% of the revenue target set forth in our board-approved projections for the 2017 fiscal year, (ii) greater than or equal to 50% of the revenue target set forth in our board-approved projections for the 2018 fiscal year, and (iii) greater than or equal to 50% of the revenue target set forth in our board-approved projections for the 2019 fiscal year. New minimum revenue levels will be established for each subsequent fiscal year by mutual agreement of us, SVB, as administrative agent, and the

lenders. The negative covenants include, among others, restrictions on us transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, creating liens, selling assets and suffering a change in control, in each case subject to certain exceptions. These covenants may make it difficult for us to operate our bu siness. In addition, we are in the early stages of commercializing NERLYNX and we cannot assure you that we will be able to achieve the minimum revenue requirements provided for in the credit facility. Our failure to satisfy the revenue, or any other, co venant could result in an event of default under the loan.

The credit facility also includes events of default, the occurrence and continuation of which could cause interest to be charged at the rate that is otherwise applicable plus 5.0% and would provide SVB, as collateral agent, with the right to exercise remedies against us and the collateral securing the credit facility, including foreclosure against the property securing the credit facilities, including our cash. These events of default include, among other things, our failure to pay principal or interest due under the credit facility, a breach of certain covenants under the credit facility, our insolvency, a material adverse change, the occurrence of any default under certain other indebtedness in an amount greater than $500,000 and one or more judgments against us in an amount greater than $500,000 individually or in the aggregate.

Even though the FDA has granted approval of NERLYNX for the treatment for the extended adjuvant treatment of early-stage, HER2-positive breast cancer, the terms of the approval may limit its commercial potential.

Even though the FDA has granted approval of NERLYNX, the scope and terms of the approval may limit our ability to commercialize NERLYNX and, therefore, our ability to generate substantial sales revenue. The FDA has approved NERLYNX only for the extended adjuvant treatment of early-stage, HER2-positive breast cancer. In connection with the FDA approval, we have committed to conduct the following post-marketing studies: (i) a physiologically-based pharmacokinetic, or PBPK, modeling/simulation study to evaluate the effect of repeat doses of a moderate CYP3A4 inhibitor on the single dose pharmacokinetics of neratinib and its active metabolites to assess the magnitude of increased drug exposure and to address the potential for excessive drug toxicity, or if the PBPK modeling/simulation is not feasible, a clinical pharmacokinetic trial, (ii) a PBPK modeling/simulation study or a clinical pharmacokinetic trial with repeat doses of a moderate CYP3A4 inducer on the single dose pharmacokinetics of neratinib and its active metabolites to assess the magnitude of decreased drug exposure and to determine appropriate dosing recommendations, (iii) a clinical pharmacokinetic trial to evaluate whether separating the dosing of H2-receptor antagonists and neratinib can minimize the drug-drug interaction potential, (iv) the submission of the final results of our 2-year carcinogenicity study in the rat, and (v) submission of certain trial data from our ongoing clinical trials. If we fail to comply with our post-marketing commitments, or if the results of the post-marketing studies, or any other ongoing clinical studies of NERLYNX, are negative, the FDA could decide to withdraw approval, add warnings or narrow the approved indication in the product label.

We are heavily dependent on the success of NERLYNX, which is still under clinical development for various additional indications. While the FDA has approved NERLYNX for the extended adjuvant treatment of patients with early stage HER2-positive breast cancer, we cannot be certain that NERLYNX will receive regulatory approval for any other indication for which we may seek approval.

The FDA has approved NERLYNX only for the extended adjuvant treatment of early stage, HER2-positive breast cancer. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to the development of NERLYNX in various additional indications. Accordingly, our business currently depends heavily on the successful development and regulatory approval of NERLYNX for additional indications. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are and will remain subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations. We are not permitted to market NERLYNX for other indications or any of our other drug candidates in the United States until they receive approval of a New Drug Application, or NDA, from the FDA, or in any foreign countries until they receive the requisite approval from such countries. In June 2016, we submitted a MAA with the European Medicines Agency, or EMA. The Committee for Medicinal Products for Human Use of the EMA, or CHMP, recently issued its Day-180 List of Outstanding issues in the process of their ongoing regulatory review of the MAA. The CHMP has requested additional data analyses related to the safety and efficacy of neratinib and has instituted a clock stop in order to allow the Company time to respond to this List of Outstanding Issues. The CHMP has set a deadline of December 22, 2017 for the Company to respond to the list. The Company expects the CHMP to issue an opinion regarding the MAA for neratinib in the first quarter of 2018. Approval of NERLYNX by the FDA for the extended adjuvant treatment of early stage, HER2-positive breast cancer does not ensure that the foreign jurisdictions will also approve NERLYNX for that indication, nor does it ensure that NERLYNX will be approved by the FDA for any other indications. Obtaining approval of an NDA or foreign marketing application is an extensive, lengthy, expensive and inherently uncertain process, and the FDA or foreign regulator may delay, limit or deny approval of a drug candidate for many reasons, including:

- we may not be able to demonstrate that NERLYNX or any other drug candidate is safe and effective as a treatment for our targeted indications to the satisfaction of the FDA or other regulator;

- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or other reg ulator for marketing approval;
- the FDA or other regulator may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the clinical research organization, or CRO, that we retain to conduct clinical trials or any other third parties involved in the conduct of trials may take actions outside of our control that materially adversely impact our clinical trials;
- the FDA or other regulator may not find the data from pre-clinical studies and clinical trials sufficient to demonstrate that the clinical and other benefits of NERLYNX or any other drug candidate outweigh the safety risks;
- the FDA or other regulator may disagree with our interpretation of data from our pre-clinical studies and clinical trials or may require that we conduct additional studies or trials;
- the FDA or other regulator may not accept data generated at our clinical trial sites;
- if our NDA is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional pre-clinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the advisory committee may recommend that the FDA require, as a condition of approval, additional pre-clinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA may require development of a Risk Evaluation and Mitigation Strategy as a condition of approval;
- the FDA or other regulator may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers; or
- the FDA or other regulator may change its approval policies or adopt new regulations.

If we do not obtain regulatory approval of NERLYNX for other indications in the United States, or for any indications in foreign jurisdictions, we will not be able to market NERLYNX for other indications or in other jurisdictions, which will limit our commercial revenue.

We will rely exclusively on third parties to formulate and manufacture NERLYNX and our drug candidates. The commercialization of NERLYNX and any of our other drug candidates, if approved, could be stopped, delayed or made less profitable if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices .

We have no experience in drug formulation or manufacturing and do not intend to establish our own manufacturing facilities. We lack the resources and expertise to formulate or manufacture our own drug candidates. While NERLYNX and our drug candidates were being developed by Pfizer, both the drug substance and drug product were manufactured by third-party contractors. We are using the same third-party contractors to manufacture, supply, store and distribute drug supplies for our clinical trials and the commercialization of NERYLNX. If we are unable to continue our relationships with one or more of these third-party contractors, we could experience delays in our development or commercialization efforts as we locate and qualify new manufacturers. We intend to rely on one or more third-party contractors to manufacture the commercial supply of our drugs. Our anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

- We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve any replacement manufacturer. This approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval.
- Our third-party manufacturers might be unable to formulate and manufacture our drugs in the volume and of the quality required to meet our clinical needs and commercial needs, as applicable.
- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products for commercialization, as applicable.
- The facilities used by our contract manufacturers to manufacture NERLYNX and our other drug candidates must be approved by the FDA pursuant to inspections that are conducted following submission of an NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacture of both active drug substances and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their

manufacturing facilities. In additio n, drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration for controlled substances, similar non-U.S. regulatory agencies and corresponding state agencies to ensure strict compliance with c GMP regulations and other government regulations and corresponding foreign standards. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our drug candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for our other drug candidates, if approved, or market NERLYNX.

- If any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to the innovation.

Each of these risks could delay our clinical trials, the approval, if any, of our drug candidates by the FDA or the commercialization of NERLYNX or our other drug candidates or result in higher costs or deprive us of potential product revenue.

If our third-party manufacturers fail to manufacture NERLYNX in sufficient quantities and at acceptable quality and pricing levels, or fail to fully comply with cGMP regulations, we may face delays in commercialization or be unable to meet market demand, and may lose potential revenues.

The manufacture of NERLYNX requires significant expertise and capital investment, including the development of advanced manufacturing techniques, process controls and the use of specialized processing equipment. Our third-party maunfacturers must comply with federal, state and foreign regulations, including the FDA's regulations governing cGMP, enforced by the FDA through its facilities inspection program and by similar regulatory authorities in other jurisdictions where we do business. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The FDA or similar foreign regulatory authorities at any time may implement new standards, or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of our products. Any failure by us or our third-party maunfacturers to comply with applicable regulations may result in fines and civil penalties, suspension of production, product seizure or recall, operating restrictions, imposition of a consent decree, modification or withdrawal of product approval or criminal prosecution and would limit the availability of our product. Any manufacturing defect or error discovered after products have been produced and distributed also could result in significant consequences, including costly recall procedures, re-stocking costs, damage to our reputation and potential for product liability claims.

If our third-party manufacturers are unable to produce the required commercial quantities of NERLYNX to meet market demand for NERLYNX on a timely basis or at all, or if they fail to comply with applicable laws for the manufacturing of NERLYNX, we will suffer damage to our reputation and commercial prospects and we will lose potential revenue.

Clinical trials are very expensive, time-consuming and difficult to design and implement.

Although the FDA approved NERLYNX for the extended adjuvant treatment of early stage, HER2-positive breast cancer in the United States on July 17, 2017, NERLYNX is still under development for various indications and our other drug candidates are in development as well, all of which will require extensive clinical testing before we can submit any NDA for regulatory approval. We cannot predict with any certainty that any NDA submitted by us will be approved by the FDA. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time consuming. We estimate that clinical trials of our other drug candidates will take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. The results of pre-clinical studies and early clinical trials of our drug candidates may not be predictive of the results of later-stage clinical trials. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our future clinical trial results may not be successful.

The commencement and completion of clinical trials may be delayed by several factors, including:

- imposition of a clinical hold or failure to obtain regulatory authorization or approval to commence a trial;
- unforeseen safety issues;
- determination of dosing issues;
- lack of effectiveness during clinical trials;
- inability to reach agreement on acceptable terms with prospective CROs and clinical trial sites;
- slower-than-expected rates of patient recruitment;

- failure to manufacture sufficient quantities of a drug candidate for use in clinical trials;
- inability to monitor patients adequately during or after treatment; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

Further, we, the FDA, foreign regulatory authorities, or an Institutional Review Board, or IRB, may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, that we are exposing participants to unacceptable health risks, or if the FDA or such other regulator finds deficiencies in our IND or comparable submissions or the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our drug candidates could be harmed, and our ability to generate revenue from the drug candidates may be delayed. In addition, any delays in our clinical trials could increase our costs, slow down the approval process and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may harm our business, financial condition and results of operations. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our drug candidates.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.

We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials. Patient enrollment and retention in clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of patients to clinical sites and the eligibility criteria for the study. Furthermore, any negative results we may report in clinical trials of any of our drug candidates may make it difficult or impossible to recruit and retain patients in other clinical studies of that same drug candidate. Delays or failures in planned patient enrollment and/or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our drug candidates, or could render further development impossible. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance.

The results of our clinical trials may not support our drug candidate claims.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support the safety and effectiveness of our drug candidates for our targeted indications. Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and pre-clinical testing. A failure of a clinical trial to meet its predetermined endpoints would likely cause us to abandon a drug candidate and may delay development of other drug candidates. Any delay in, or termination of, our clinical trials will delay the filing of our NDAs with the FDA and, ultimately, our ability to commercialize our drug candidates and generate product revenue.

While we have negotiated a Special Protocol Assessment, or SPA, agreement with the FDA relating to our Phase III clinical study of PB272, this agreement does not guarantee approval of PB272 or any other particular outcome from regulatory review of the clinical trial or the drug candidate.

In February 2013, we announced that we reached agreement with the FDA under a Special Protocol Assessment, or SPA, for our Phase III clinical trial of PB272 in patients with HER2-positive metastatic breast cancer who have failed two or more prior treatments. We commenced the Phase III clinical trial in June 2013. The FDA's SPA process is designed to facilitate the FDA's review and approval of drugs by allowing the FDA to evaluate the proposed design and size of Phase III clinical trials that are intended to form the primary basis for determining a drug product's efficacy. Upon specific request by a clinical trial sponsor, the FDA will evaluate the protocol and respond to a sponsor's questions regarding, among other things, primary efficacy endpoints, trial conduct and data analysis, within 45 days of receipt of the request. The FDA ultimately assesses whether the protocol design and planned analysis of the trial are acceptable to support regulatory approval of the product candidate with respect to the effectiveness of the identified indication. All agreements between the FDA and the sponsor regarding an SPA must be clearly documented in writing, either in the form of an SPA letter or minutes of a meeting between the sponsor and the FDA at which the SPA agreement was reached. However, an SPA agreement does not guarantee approval of a product candidate, and even if the FDA agrees to the design, execution, and analysis proposed in protocols reviewed under the SPA process, the FDA may revoke or alter its agreement in certain circumstances. In particular, an SPA agreement is not binding on the FDA if public health concerns emerge that were unrecognized at the time of the SPA agreement, other new scientific concerns regarding product safety or efficacy arise, the sponsor company fails to comply with the agreed upon trial protocols, or the relevant data, assumptions or information provided by the sponsor in a request for

the SPA change or are found to be false or omit releva nt facts. In addition, even after an SPA agreement is finalized, the SPA agreement may be modified, and such modification will be deemed binding on the FDA review division, except under the circumstances described above, if the FDA and the sponsor agree in writing to modify the protocol and such modification is intended to improve the study. The FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from any study that is the subject of the SP A agreement.

We cannot assure you that our Phase III clinical trial will succeed, or that the SPA will ultimately be binding on the FDA or will result in any FDA approval for PB272. The trial is expected to enroll approximately 600 patients. We expect that the FDA will review our compliance with the SPA, evaluate the results of the clinical trials and conduct inspections of some of the approximately 250 sites in North America, Europe and Asia-Pacific where the clinical trials will be conducted. We cannot assure you that each of the clinical trial sites will pass such FDA inspections, and negative inspection results could significantly delay or prevent any potential approval for PB272. If the FDA revokes or alters its agreement under the SPA, or interprets the data collected from the clinical trial differently than we do, the FDA may deem the data insufficient to support regulatory approval, which could materially adversely affect our business, financial condition and results of operations.

NERLYNX or our other drug candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any, as applicable.

Undesirable side effects caused by NERLYNX or our other drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. To date, subjects treated with NERLYNX have experienced drug-related side effects including diarrhea. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if we or others later identify undesirable side effects caused by any approved product, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of NERLYNX or the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated as set forth on the product label. If we market NERLYNX for uses beyond such approved indications, we could be subject to enforcement action, which could have a material adverse effect on our business.

The FDA strictly regulates marketing, labeling, advertising and promotion of prescription drugs. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the internet and off-label promotion. Any regulatory approval that the FDA grants is limited to those specific diseases and indications for which a product is deemed to be safe and effective by the FDA. For example, the FDA-approved label for NERLYNX is limited to the extended adjuvant treatment of early stage, HER2-positive breast cancer. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our drugs and drug candidates, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

While physicians in the United States may choose, and are generally permitted, to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, our ability to promote the products is narrowly limited to those indications that are specifically approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances.

Regulatory authorities in the United States generally do not regulate the behavior of physicians in their choice of treatments. Regul atory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. Although recent court decisions suggest that certain off-label promotional activities may be protected under the First Amendment, the scope of any such protection is unclear. If our promotional activities fail to comply with the FDA's regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guid elines relating to promotion and advertising may cause the FDA to issue warning letters or untitled letters, bring an enforcement action against us, suspend or withdraw an approved product from the market, require a recall or institute fines or civil fines , or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our reputation and our business.

Even though the FDA has approved NERLYNX for the extended adjuvant treatment of early stage, HER2-positive breast cancer, we will be subject to ongoing obligations and continued regulatory review with regard to NERLYNX and any other drug candidates that receive FDA approval, which may result in significant additional expense. Additionally, NERLYNX and our drug candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

The FDA's approval of the NDA for NERLYNX may, and any regulatory approvals that we receive for our other drug candidates may, also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the drug candidate. In addition, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Notably, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, that requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. It is difficult to predict how these requirement will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

We rely on third parties to conduct our pre-clinical studies and clinical trials. If these third parties do no t successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for our drug candidates.

We depend upon independent investigators and collaborators, such as CROs, universities and medical institutions, to conduct our pre-clinical studies and clinical trials under agreements with us. These collaborators are not our employees and we cannot control the amount or timing of resources that they devote to our programs. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with regulatory requirements, including good clinical practice, or GCP, requirements, and the applicable protocol. If we, or any of our CROs or third party contractors, fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under current cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, third party contractors and investigators may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. If outside collaborators fail to devote sufficient time and resources to our drug-development programs, or if their performance is substandard or otherwise fails to satisfy applicable regulatory requirements, the approval of our FDA applications, if any, and our introduction of new drugs, if any, will be delayed. These collaborators may also have relationships with other commercial entities, some of whom may compete with us. If our collaborators assist our competitors to our detriment, our competitive position would be harmed. If any of our relationships with these third-party collaborators terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, or at all. Switching or adding additional third parties to our clinical trial programs can involve substantial costs and require extensive management time and focus.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.

Our internal computer systems and those of third parties with which we contract may be vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures despite the implementation of security measures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our research and development programs and the development of our drug candidates could be delayed.

Health care reform measures may hinder or prevent our products' and product candidates' commercial success.

The United States and some foreign jurisdictions have enacted or are considering enacting a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to profitably sell our product and product candidates, if and when they are approved. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, became law in the United States. The ACA substantially changed and will continue to change the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Among the provisions of the ACA, of greatest importance to the pharmaceutical industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;

- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals, which began in April 2010, and by adding new eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level beginning in 2014, thereby potentially increasing manufacturers' Medicaid rebate liability;
- increase in the number of entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians;
- a licensure framework for follow-on biologic products; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

The ACA also requires adults not covered by employer or government-sponsored insurance plans to maintain health insurance coverage or pay a penalty, a provision commonly referred to as the individual mandate.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the ACA. We expect that the Trump administration and U.S. Congress will continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA. We cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments, will remain in effect through 2030 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or ATRA, which, among other things, also reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Recently, there has also been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, the 21st Century Cures Act changes the reimbursement methodology for infusion drugs and biologics furnished through durable medical equipment in an attempt to remedy over- and underpayment of certain drugs. We cannot predict all of the ways in which future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs.

We anticipate that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product and product candidates, if approved.

Failure to obtain or maintain adequate coverage and reimbursement for our products or product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

Successful commercial sales of any approved products will depend on the availability of adequate coverage and reimbursement from government health administration authorities, private health insurers and other third-party payors. Each third-party payor

separately decides which products it will cover and establishes the reimbursement level, and there is no guarantee that any of our approved products or product candidates that may be approved for marketing by regulatory authorities will receive adequate coverage or reimbursement levels. Obtaining and maintaining coverage approval for a product is time-consuming, costly and may be difficult. We may be req uired to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of coverage and reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or limited, we may not be able to suc cessfully commercialize any product or product candidate for which we obtain marketing approval. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drugs and biologics. Even if we obtain coverage for a given product, the resulting reim bursement rates may be inadequate and may affect the demand for, or the price of, any product candidate for which we obtain marketing approval.

We expect to experience pricing pressures in connection with the sale of NERLYNX (oral), NERLYNX (intravenous), PB357 and any other products that we may develop, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. There may be additional pressure by payors and healthcare providers to use generic drugs that contain the active ingredients found in neratinib (oral), neratinib (intravenous), PB357 or any other drug candidates that we may develop. If we fail to successfully secure and maintain adequate coverage and reimbursement for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and expected revenue and profitability which would have a material adverse effect on our business, results of operations and financial condition.

We are subject, directly and indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, physician payment transparency laws and health information privacy and security laws. Failure to comply with these laws may subject us to substantial penalties.

We do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors. However, federal and state healthcare laws and regulations pertaining to fraud and abuse, physician payment transparency, privacy and security laws and regulations may apply to us depending on programs we operate and have been asserted by the government and others to apply to companies like us, and our arrangements with healthcare providers, customers and other entities, including our marketing practices, educational programs and pricing policies. These laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs. The Affordable Care Act amended the federal Anti-Kickback Statute to provide that a person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- federal false claims laws, including, without limitation, the False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal third-party payors that are false or fraudulent, such as engaging in improper promotion of products or submitting inaccurate price reports to the Medicaid Drug Rebate program;
- the federal Civil Monetary Penalties law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- federal criminal laws that prohibit executing a scheme to defraud any federal healthcare benefit program or making false statements relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information held by certain covered entities and their business associates, and imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to Centers for Medicare & Medicaid Services ("CMS") information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists

and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to CMS ownership an d investment interests held by the physicians described above and their immediate family members and payments or other "transfers of value" to such physician owners (manufacturers are required to submit reports to CMS by the 90th day of each calendar year) ;

- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under such laws, it is possible that some of our business activities, including our relationships with physicians and other healthcare providers, some of whom recommend, purchase and/or prescribe our products, and the manner in which we promote our products, could be subject to challenge under one or more of such laws.

We are also exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors, distributors and agents may engage in fraudulent or other illegal activity. While we have policies and procedures in place prohibiting such activity, misconduct by these parties could include, among other infractions or violations, intentional, reckless and/or negligent conduct or unauthorized activity that violates FDA requirements, including those laws that require the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare fraud and abuse laws and regulations, laws that require the true, complete and accurate reporting of financial information or data or other commercial or regulatory laws or requirements. It is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

If our operations are found to violate any of the laws described above or any other laws and regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment of officers involved, any of which could adversely affect our ability to market our current and any future products, once approved, and materially adversely affect our business, results of operations and financial condition. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the United States, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, results of operations and financial condition.

We participate in the Medicaid Drug Rebate Program, as administered by the CMS, and other federal and state government pricing programs in the United States, and we may participate in additional government pricing programs in the future. These programs generally require us to pay rebates or otherwise provide discounts to government payors in connection with drugs, including NERLYNX, that are dispensed to beneficiaries of these programs. In some cases, such as with the Medicaid Drug Rebate Program, the rebates are based on pricing and rebate calculations that we report on a monthly and quarterly basis to the government agencies that administer the programs. Pricing and rebate calculations are complex, vary among products and programs, and are often subject to interpretation by governmental or regulatory agencies and the courts. The terms, scope and complexity of these government pricing programs change frequently. Responding to current and future changes may increase our costs and the complexity of compliance will be time consuming.

In addition, there is increased focus by the Office of Inspector General on the methodologies used by manufacturers to calculate average manufacturer price ("AMP"), and best price ("BP"), to assess manufacturer compliance with reporting requirements under the Medicaid Drug Rebate Program. We are liable for errors associated with our submission of pricing data and for any overcharging of government payors. For example, failure to submit monthly/quarterly AMP and BP data on a timely basis could result in a civil monetary penalty per day for each day the submission is late beyond the due date. Failure to make necessary disclosures and/or to identify overpayments could result in allegations against us under the Federal False Claims Act and other laws and regulations.

Any required refunds to the U.S. government or responding to a government investigation or enforcement action would be expensive and time consuming and could have a material adverse effect on our business, results of operatio ns and financial condition. In the event that the CMS were to terminate our rebate agreement, no federal payments would be available under Medicaid or Medicare for our covered outpatient drugs.

If we cannot compete successfully for market share against other drug companies, we may not achieve sufficient product revenue and our business will suffer.

The market for our drugs and drug candidates is characterized by intense competition and rapid technological advances. NERLYNX and any of our other drug candidates that receives FDA approval will compete with a number of existing and future drugs and therapies developed, manufactured and marketed by others. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. In addition, a large number of companies are pursuing the development of pharmaceuticals that target the same diseases and conditions that we are targeting. If our products fail to capture and maintain market share, we may not achieve sufficient product revenue and our business will suffer.

We will compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have oncology compounds that have already been approved or are in development. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs or have substantially greater financial resources than we do, as well as significantly greater experience in the following:

- developing drugs;
- undertaking pre-clinical testing and clinical trials;
- obtaining FDA and other regulatory approvals of drugs;
- formulating and manufacturing drugs; and
- launching, marketing and selling drugs.

We may be exposed to liability claims associated with the use of hazardous materials and chemicals.

Our research and development activities may involve the controlled use of hazardous materials and chemicals. Although we believe that our safety procedures for using, storing, handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot completely eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, we could be held liable for any resulting damages and any liability could materially adversely affect our business, financial condition and results of operations. In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require us to incur substantial compliance costs that could materially adversely affect our business, financial condition and results of operations.

The loss of one or more key members of our management team could adversely affect our business.

Our success and future growth depends to a significant degree on the skills and continued services of our management team, in particular Alan H. Auerbach, our Chief Executive Officer and President. If Mr. Auerbach resigns or becomes unable to continue in his present role and is not adequately replaced, our business operations could be materially adversely affected. We do not maintain “key man” life insurance for Mr. Auerbach.

If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed.

As of September 30, 2017, we had 308 employees, including our Chief Executive Officer and President. Our future success depends on our ability to identify, attract, hire, train, retain and motivate other highly skilled scientific, technical, marketing, managerial and financial personnel. Although we will seek to hire and retain qualified personnel with experience and abilities commensurate with our needs, there is no assurance that we will succeed despite their collective efforts. Competition for personnel is intense, and any failure to attract and retain the necessary technical, marketing, managerial and financial personnel would have a material adverse effect on our business, prospects, financial condition and results of operations.

We may not successfully manage our growth.

Our success will depend upon the expansion of our operations and our ability to successfully manage our growth. Our future growth, if any, may place a significant strain on our management and on our administrative, operational and financial resources. Our ability to manage our growth effectively will require us to implement and improve our operational, financial and management systems and to expand, train, manage and motivate our employees. These demands may require the hiring of additional management personnel and the development of additional expertise by management. Any increase in resources devoted to research and product development without a corresponding increase in our operational, financial and management systems could have a material adverse effect on our business, financial condition and results of operations.

We may be adversely affected by the current economic environment.

Our ability to attract and retain collaborators or customers, invest in and grow our business and meet our financial obligations depends on our operating and financial performance, which, in turn, is subject to numerous factors, including the prevailing economic conditions and financial, business and other factors beyond our control, such as the rate of unemployment, the number of uninsured persons in the United States and inflationary pressures. We cannot anticipate all the ways in which the current economic climate and financial market conditions could adversely impact our business.

We are exposed to risks associated with reduced profitability and the potential financial instability of our collaborators or customers, many of which may be adversely affected by volatile conditions in the financial markets. For example, unemployment and underemployment, and the resultant loss of insurance, may decrease the demand for healthcare services and pharmaceuticals. If fewer patients are seeking medical care because they do not have insurance coverage, our collaboration partners or customers may experience reductions in revenues, profitability and/or cash flow that could lead them to modify, delay or cancel orders for our products once commercialized. If collaboration partners or customers are not successful in generating sufficient revenue or are precluded from securing financing, they may not be able to pay, or may delay payment of, accounts receivable that are owed to us. This, in turn, could adversely affect our financial condition and liquidity. In addition, if economic challenges in the United States result in widespread and prolonged unemployment, either regionally or on a national basis, prior to the effectiveness of certain provisions of the ACA, a substantial number of people may become uninsured or underinsured. To the extent economic challenges result in fewer individuals pursuing or being able to afford our products once commercialized, our business, results of operations, financial condition and cash flows could be adversely affected.

We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.

The testing and marketing of medical products entail an inherent risk of product liability. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. If we are unable to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims, the commercialization of pharmaceutical products we develop, alone or with collaborators, could be prevented or inhibited.

Our cash and cash equivalents could be adversely affected if the financial institutions in which we hold our cash and cash equivalents fail.

We regularly maintain cash balances at third-party financial institutions in excess of the Federal Deposit Insurance Corporation, or FDIC, insurance limit. While we monitor daily the cash balances in the operating accounts and adjust the balances as appropriate, these balances could be impacted, and there could be a material adverse effect on our business, if one or more of the financial institutions with which we deposit fails or is subject to other adverse conditions in the financial or credit markets. To date, we have experienced no loss or lack of access to our invested cash or cash equivalents; however, we can provide no assurance that access to our invested cash and cash equivalents will not be impacted by adverse conditions in the financial and credit markets.

Our investments in marketable securities are subject to market, interest and credit risk that may reduce their value.

The value of our investments in marketable securities may be adversely affected by changes in interest rates, downgrades in the creditworthiness of bonds we hold, turmoil in the credit markets and financial services industry and by other factors which may result in other than temporary declines in the value of our investments. Decreases in the market value of our marketable securities could have an adverse impact on our consolidated financial statements, results of operations and cash flow.

Risks Related to Our Intellectual Property

We depend significantly on intellectual property licensed from Pfizer and the termination of this license would significantly harm our business and future prospects.

We depend significantly on our license agreement with Pfizer. Our license agreement with Pfizer may be terminated by Pfizer if we materially breach the agreement and fail to cure our breach during an applicable cure period. Our failure to use commercially reasonable efforts to develop and commercialize licensed products in certain specified major market countries would constitute a material breach of the license agreement. Pfizer may also terminate the license agreement if we become involved in bankruptcy, receivership, insolvency or similar proceedings. In the event our license agreement with Pfizer is terminated, we will lose all of our rights to develop and commercialize the drug candidates covered by such license, which would significantly harm our business and future prospects.

Our proprietary rights may not adequately protect our intellectual property and potential products, and if we cannot obtain adequate protection of our intellectual property and potential products, we may not be able to successfully market our potential products.

Our commercial success will depend in part on obtaining and maintaining intellectual property protection for our products, formulations, processes, methods and other technologies. We will only be able to protect these technologies and products from unauthorized use by third parties to the extent that valid and enforceable intellectual property rights, including patents, cover them, or other market exclusionary rights apply. The patent positions of pharmaceutical companies, like ours, can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies' patents has emerged to date in the United States. The general environment for pharmaceutical patents outside the United States also involves significant uncertainty. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced, or that the scope of these patent rights could provide a sufficient degree of future protection that could permit us to gain or keep our competitive advantage with respect to these products and technology. For example, we cannot predict:

- the degree and range of protection any patents will afford us against competitors, including whether third parties will find ways to make, use, sell, offer to sell or import competitive products without infringing our patents;
- if and when patents will issue;
- whether or not others will obtain patents claiming inventions similar to those covered by our patents and patent applications; or
- whether we will need to initiate litigation or administrative proceedings in connection with patent rights, which may be costly whether we win or lose.

The patents we have licensed may be subject to challenge and possibly invalidated or rendered unenforceable by third parties. Changes in either the patent laws or in the interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property.

In addition, others may independently develop similar or alternative products and technologies that may be outside the scope of our intellectual property. Furthermore, others may have invented technology claimed by our patents before we or our licensors did so, and they may have filed patents claiming such technology before we did so, weakening our ability to obtain and maintain patent protection for such technology. Should third parties obtain patent rights to similar products or technology, this may have an adverse effect on our business.

We may also rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. Trade secrets, however, are difficult to protect. While we believe that we will use reasonable efforts to protect our trade secrets, our own or our strategic partners' employees, consultants, contractors or advisors may unintentionally or willfully disclose our information to competitors. We seek to protect this information, in part, through the use of non-disclosure and confidentiality agreements with employees, consultants, advisors and others. These agreements may be breached, and we may not have adequate remedies for a breach. In addition, we cannot ensure that those agreements will provide adequate protection for our trade secrets, know-how or other proprietary information or prevent their unauthorized use or disclosure.

To the extent that consultants or key employees apply technological information independently developed by them or by others to our potential products, disputes may arise as to the proprietary rights in such information, which may not be resolved in our favor. Consultants and key employees who work with our confidential and proprietary technologies are required to assign all intellectual property rights in their discoveries to us. However, these consultants or key employees may terminate their relationship with us, and we cannot preclude them indefinitely from dealing with our competitors. If our trade secrets become known to competitors with greater experience and financial resources, the competitors may copy or use our trade secrets and other proprietary information in the

advancement of their products, methods or technologies. If we were to prosecute a claim that a third party ha d illegally obtained and was using our trade secrets, it could be expensive and time consuming and the outcome could be unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets than courts in the Unit ed States. Moreover, if our competitors independently develop equivalent knowledge, we would lack any legal or contractual claim to prevent them from using such information, and our business could be harmed.

Our ability to commercialize our potential products will depend on our ability to sell such products without infringing the patent or proprietary rights of third parties. If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Our ability to commercialize our potential products will depend on our ability to sell such products without infringing the patents or other proprietary rights of third parties. Third-party intellectual property rights in our field are complicated and continuously evolving. The coverage of patents is subject to interpretation by the courts, and this interpretation is not always consistent.

Other companies may have or may acquire intellectual property rights that could be enforced against us. If they do so, we may be required to alter our products, formulations, processes, methods or other technologies, obtain a license, assuming one can be obtained, or cease our product-related activities. If our products or technologies infringe the intellectual property rights of others, they could bring legal action against us or our licensors or collaborators claiming damages and seeking to enjoin any activities that they believe infringe their intellectual property rights. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving the invalidity of a patent is particularly difficult in the United States, since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. If we are found to infringe a third-party patent, we may need to cease the commercial sale of our products.

Because patent applications can take many years to issue, there may be currently pending applications unknown to us or reissue applications that may later result in issued patents upon which our products or technologies may infringe. There could also be existing patents of which we are unaware that our products or technologies may infringe. In addition, if third parties file patent applications or obtain patents claiming products or technologies also claimed by us in pending applications or issued patents, we may have to participate in interference proceedings in the U.S. Patent and Trademark Office, or USPTO, to determine priority of invention. If third parties file oppositions in foreign countries, we may also have to participate in opposition proceedings in foreign tribunals to defend the patentability of our filed foreign patent applications. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Additionally, any uncertainties resulting from the initiation and continuation of any litigation may have a material adverse effect on our ability to raise the funds necessary to continue our operations.

If a third party claims that we infringe its intellectual property rights, it could cause our business to suffer in a number of ways, including:

- we may become involved in time-consuming and expensive litigation, even if the claim is without merit, the third party’s patent is ultimately invalid or unenforceable, or we are ultimately found to have not infringed;
- we may become liable for substantial damages for past infringement if a court decides that our technologies infringe upon a third party’s patent;
- we may be ordered by a court to stop making, selling or licensing our products or technologies without a license from a patent holder, and such license may not be available on commercially acceptable terms, if at all, or may require us to pay substantial royalties or grant cross-licenses to our patents; and
- we may have to redesign our products so that they do not infringe upon others’ patent rights, which may not be possible or could require substantial investment and/or time.

If any of these events occur, our business could suffer and the market price of our common stock may decline.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other companies in these industries, including our competitors or potential competitors. We may become subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, although no such claims are pending. Litigation may be necessary to defend against these claims. Even if we successfully defend any such claims, we may incur substantial costs in such defense, and our management may be distracted by these claims.

Risks Related to Owning our Common Stock

Our stock price may fluctuate significantly and you may have difficulty selling your shares based on current trading volumes of our stock. In addition, numerous other factors could result in substantial volatility in the trading price of our stock.

We cannot predict the extent to which investor interest in our company will be sufficient to maintain an active trading market on the NASDAQ Global Select Market or any other exchange in the future. We have several stockholders, including affiliated stockholders, who hold substantial blocks of our stock. As of September 30, 2017 we estimate that our officers, directors and their affiliated entities, and our 5% or greater stockholders, collectively beneficially owned approximately 89.9% of our outstanding shares of common stock. Sales of large numbers of shares by any of our large stockholders could adversely affect our trading price. If stockholders holding shares of our common stock sell, indicate an intention to sell, or if it is perceived that they will sell, substantial amounts of their common stock in the public market, the trading price of our common stock could decline. Moreover, if there is a less active trading market, holders of our common stock may have difficulty selling their shares.

The price of our common stock could be subject to volatility related or unrelated to our operations.

The trading price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

- our ability to successfully commercialize NERLYNX in the United States for the extended adjuvant treatment of early stage, HER2-positive breast cancer;
- the status and cost of our marketing commitments for NERLYNX;
- the status and cost of development and commercialization of neratinib for indications other than in the treatment of HER2-positive breast cancer and in jurisdictions other than in the United States, if approved;
- actual or anticipated quarterly variation in our results of operations or the results of our competitors;
- announcements regarding results of any clinical trials relating to our drug candidates;
- announcements of medical innovations or new products by our competitors;
- issuance of new or changed securities analysts' reports or recommendations for our stock;
- developments or disputes concerning our intellectual property or other proprietary rights;
- commencement of, or involvement in, litigation;
- market conditions in the biopharmaceutical industry;
- timing and announcement of regulatory approvals;
- any future sales of our common stock or other securities in connection with raising additional capital or otherwise;
- any major change to the composition of our board of directors or management; and
- general economic conditions and slow or negative growth of our markets.

The stock market in general, and market prices for the securities of biotechnology companies like ours in particular, have from time to time experienced volatility that often has been unrelated to the operating performance of the underlying companies. These broad market and industry fluctuations may adversely affect the market price of our common stock, regardless of our operating performance.

Volatility in the price of our common stock may subject us to securities litigation, which could cause us to incur substantial costs and divert management's attention, financial resources and other company assets.

In the past, securities class action litigation has often been brought against a company following periods of volatility in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. In addition, we and certain of our executive officers have been named as defendants in a securities class action and derivative lawsuits captioned HSC v. Puma Biotechnology, Inc., et al., Xing Xie v. Alan H. Auerbach, and Kevin McKenney v. Auerbach. These lawsuits and any future lawsuits to which we may become a party are subject to inherent uncertainties and will likely be expensive and time-consuming to investigate, defend and resolve, and will divert our management's attention and financial and other resources. The outcome of litigation is necessarily uncertain, and we could be forced to expend significant resources in the defense of these and other suits, and we may not prevail. Any litigation to which we are a party may result in an onerous or unfavorable judgment that may not be reversed upon appeal or in payments of substantial monetary damages or fines, or we may decide to settle this or other lawsuits on similarly unfavorable terms, which could adversely affect our business, financial

condition, results of operations or stock price. See Item 3. "Legal Proceedings" below for additional information regarding the securities class action and derivative lawsuits.

Issuance of stock to fund our operations may dilute your investment and reduce your equity interest.

We may need to raise capital in the future to fund the development of our drug candidates or for other purposes. Any equity financing may have a significant dilutive effect to stockholders and a material decrease in our existing stockholders' equity interest in us. Equity financing, if obtained, could result in substantial dilution to our existing stockholders. At its sole discretion, our board of directors may issue additional securities without seeking stockholder approval, and we do not know when we will need additional capital or, if we do, whether it will be available to us.

Upon the exercise of our outstanding warrant, holders of our common stock may experience immediate dilution and the market price of our common stock may be adversely affected.

Following an October 2011 private placement, Alan H. Auerbach, our founder, Chief Executive Officer and President, held approximately 21% of our outstanding shares of common stock. Pursuant to the terms of the Securities Purchase Agreement for the private placement, we issued an anti-dilutive warrant to Mr. Auerbach. The warrant has a 10-year term expiring in October 2021 for 2,116,250 shares with an exercise price of $16.00 per share.

If any portion of the outstanding warrant is exercised for shares of our common stock, our stockholders may experience immediate dilution and the market price of our common stock may be adversely affected.

We will incur increased costs and demands upon management as a result of complying with the laws and regulations affecting public companies, which could harm our operating results.

As a public company, we incur significant legal, accounting and other expenses, including costs associated with public company reporting requirements. We also incur costs associated with current corporate governance requirements, including requirements under Section 404 and other provisions of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, as well as rules implemented by the SEC, or NASDAQ or any stock exchange or inter-dealer quotations system on which our common stock may be listed in the future. The expenses incurred by public companies for reporting and corporate governance purposes have increased dramatically in recent years. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly. We are unable to currently estimate these costs with any degree of certainty. We also expect that these rules and regulations may make it difficult and expensive for us to maintain the appropriate level of director and officer insurance for a company with our market capitalization. If we are unable to maintain an appropriate level of such insurance, we may be required to accept reduced policy limits and coverage or larger deductible limits. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as our executive officers.

If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, our ability to operate our business and investors' views of us.

We are subject to the rules and regulations of the SEC, including those rules and regulations mandated by the Sarbanes-Oxley Act. Section 404 of the Sarbanes-Oxley Act requires public companies to include in their annual report a statement of management's responsibilities for establishing and maintaining adequate internal control over financial reporting, together with an assessment of the effectiveness of those internal controls. Section 404 also requires the independent auditors of certain public companies to attest to, and report on, this management assessment. Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that will need to be evaluated frequently. Our failure to maintain the effectiveness of our internal controls in accordance with the requirements of the Sarbanes-Oxley Act could have a material adverse effect on our business. We could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on the price of our common stock. In addition, if our efforts to comply with new or changed laws, regulations, and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Sales of a substantial number of shares of our common stock in the public market could cause the market price of our common stock to drop significantly, even if our business is doing well, which result would in turn negatively affect our ability to raise additional equity capital.

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. A substantial majority of the outstanding shares of our common stock are freely tradable without restriction or further registration under the Securities Act of

1933, as amended. We have also registered all shares of common stock that we may issue under our equity compensation plan, which can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates. We are unable to predict the effect that sales may have on the prevailing market price of our common stock. However, an adverse effect on the market price of our common stock could have a material adverse effect on our ability to raise addit ional equity capital.

If securities or industry analysts do not publish, or cease publishing, research or reports about us, our business or our market, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock is and will be influenced by whether industry or securities analysts publish research and reports about us, our business, our market or our competitors and, if any analysts do publish such reports, what they publish in those reports. We may not obtain analyst coverage in the future. Any analysts who do cover us may make adverse recommendations regarding our stock, adversely change their recommendations from time to time, and/or provide more favorable relative recommendations about our competitors. If any analyst who may cover us in the future were to cease coverage of our company or fail to regularly publish reports on us, or if analysts fail to cover us or publish reports about us at all, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

We do not foresee paying cash dividends in the foreseeable future.

We currently intend to retain any future earnings for funding growth. We do not anticipate paying any dividends in the foreseeable future. As a result, you should not rely on an investment in our securities if you require dividend income. Capital appreciation, if any, of our shares may be your sole source of gain for the foreseeable future. Moreover, you may not be able to re-sell your shares in us at or above the price you paid for them.

Our ability to use our net operating losses and research and development credit carryforwards to offset future taxable income may be subject to certain limitations.

In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three year period, is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, and its research and development credit carryforwards to offset future taxable income. Our existing NOLs and research and development credit carryforwards may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change, our ability to utilize NOLs and research and development credit carryforwards could be further limited by Sections 382 and 383 of the Code. Future changes in our stock ownership, some of which might be beyond our control, could result in an ownership change under Sections 382 and 383 of the Code. Furthermore, our ability to utilize NOLs and research and development credit carryforwards of any companies we may acquire in the future may be subject to limitations, in accordance with Sections 382 and 383 of the Code. For these reasons, in the event we experience a change of control, we may not be able to utilize a material portion of the NOLs and research and development credit carryforwards, even if we attain profitability.

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 quarter ended September 30, 2017.

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, 2017.

Item 3. DEFAULTS UPON SENIOR SECURITIES

None.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Item 5. OTHER INFORMATION

On September 29, 2017, the compensation committee of our board of directors approved the ratification, or the Ratification, of certain grants of Restricted Stock Units, or the RSU Awards, under the Puma Biotechnology, Inc. 2011 Incentive Award Plan, as amended, pursuant to and in accordance with Section 204 of the General Corporation Law of the State of Delaware, or the General Corporation Law. The RSU Awards were made on May 1, 2017, May 8, 2017, May 22, 2017, May 30, 2017, June 12, 2017, June 19, 2017, June 26, 2017, July 17, 2017, July 24, 2017, July 31, 2017, August 7, 2017 and August 14, 2017 and involved the grant of 7,500, 11,250, 35,625, 3,750, 30,000, 30,000, 18,750, 24,375, 18,750, 15,000, 11,250 and 11,250 Restricted Stock Units, respectively. The compensation committee approved the Ratification of such RSU Awards after it determined that the RSU Awards may not have been duly authorized in accordance with Section 152 of the General Corporation Law. As none of the RSU Awards have vested, no shares of putative stock have been issued in respect of the RSU Awards. Any claim that the RSU Awards are void or voidable due to the foregoing failure of authorization, or that the Court of Chancery of the State of Delaware should declare in its discretion that the Ratification not be effective or be effective only on certain conditions, must be brought within 120 days from the later of the validation effective time and the giving of this notice (which is deemed given on the date that this Quarterly Report on Form 10-Q is filed with the Securities and Exchange Commission).

Item 6. EXHIBITS

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

Exhibit	Description
3.1	Second Amended and Restated Certificate of Incorporation of the Company, as filed with the Secretary of State of the State of Delaware on June 14, 2016 (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on June 15, 2016 and incorporated herein by reference)
3.2	Second Amended and Restated Bylaws of the Company (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on May 8, 2017 and incorporated herein by reference)
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, 2017
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, 2017
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Linkbase Document

+ Management contract or compensatory plan or arrangement

SIGNAT URES

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

PUMA BIOTECHNOLOGY, INC.

Date: November 9, 2017

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

Date: November 9, 2017

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

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, 2017;

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 9, 2017

/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, Charles R. Eyler, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended September 30, 2017;

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 9, 2017

/s/ Charles R. Eyler
Charles R. Eyler
Principal Financial and Accounting 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, 2017, 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, 2017, 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 9, 2017

/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, 2017, pursuant to 18 U.S.C. § 1350 and in accordance with SEC Release No. 33-8238. This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference in any filing of Puma Biotechnology, Inc. under the Securities Act of 1933, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Certification of Principal Financial Officer

I, Charles R. Eyler, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended September 30, 2017, 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 9, 2017

/s/ Charles R. Eyler
Charles R. Eyler
Principal Financial and Accounting Officer

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