PUMA BIOTECHNOLOGY, INC.
Form 10-Q
August 09, 2018

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 June 30, 2018

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission File Number: 001-35703

PUMA BIOTECHNOLOGY, INC.

(Exact name of registrant as specified in its charter)

Delaware	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. 38,024,982 shares of Common Stock, par value $0.0001 per share, were outstanding as of August 6, 2018.

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PUMA BIOTECHNOLOGY, INC.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

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

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

These statements are often, but not always, made through the use of words or phrases such as “anticipate,” “estimate,” “plan,” “project,” “continuing,” “ongoing,” “expect,” “believe,” “intend” and similar words or phrases. Accordingly, these state involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. Discussions containing these forward-looking statements may be found throughout this Quarterly Report on Form 10-Q, including, in Part I, the section entitled “Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.” These forward-looking statements involve risks and uncertainties, including the risks discussed in Part I, Item 1A. “Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2017 that could cause our actual results to differ materially from those in the forward-looking statements. Such risks should be considered in evaluating our prospects and future financial performance. We undertake no obligation to update the forward-looking statements or to reflect events or circumstances after the date of this document.

Part I – FINANCIAL INFORMATION

Item 1. Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share data)

(unaudited)

	June 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$95,912	$81,698
Marketable securities	38,600	—
Accounts receivable, net	21,343	9,670
Inventory	2,475	2,029
Prepaid expenses and other, current	11,730	12,997
Total current assets	170,060	106,394
Property and equipment, net	4,311	4,470
Prepaid expenses and other, long-term	2,551	1,989
Intangible assets, net	46,382	48,355
Restricted cash	4,317	4,317
Total assets	$227,621	$165,525
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$22,336	$27,692
Accrued expenses	41,194	30,648
Total current liabilities	63,530	58,340
Deferred rent	5,523	5,406
Long-term debt	120,269	48,477
Total liabilities	189,322	112,223
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Common stock - $.0001 par value per share; 100,000,000 shares authorized; 37,890,220 shares issued and outstanding at June 30, 2018 and 37,594,851 issued and outstanding at December 31, 2017	4	4
Additional paid-in capital	1,195,600	1,142,213
Receivable from exercise of stock options	(159)	(449)
Accumulated other comprehensive loss	(1)	—
Accumulated deficit	(1,157,145)	(1,088,466)
Total stockholders' equity	38,299	53,302
Total liabilities and stockholders' equity	$227,621	$165,525

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share data)

(unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2018	2017	2018	2017
Revenue:				
Product revenue, net	$50,767	$—	$86,783	$—
License revenue	—	—	30,500	—
Total revenue	50,767	—	117,283	—
Operating costs and expenses:				
Cost of sales	8,831	—	15,214	—
Selling, general and administrative	40,135	24,929	76,737	43,330
Research and development	43,245	53,253	90,169	108,054
Total operating costs and expenses	92,211	78,182	182,120	151,384
Loss from operations	(41,444)	(78,182)	(64,837)	(151,384)
Other (expenses) income:				
Interest income	329	380	503	730
Interest expense	(2,587)	—	(3,666)	—
Other expenses	(633)	(30)	(679)	(43)
Total other (expenses) income:	(2,891)	350	(3,842)	687
Net loss	$(44,335)	$(77,832)	$(68,679)	$(150,697)
Net loss applicable to common stockholders	$(44,335)	$(77,832)	$(68,679)	$(150,697)
Net loss per common share—basic and diluted	$(1.17)	$(2.10)	$(1.82)	$(4.08)
Weighted-average common shares outstanding—basic and diluted	37,819,767	36,992,017	37,759,729	36,961,760

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 June 30,		For the Six Months Ended June 30,	
	2018	2017	2018	2017
Net loss	$(44,335)	$(77,832)	$(68,679)	$(150,697)
Other comprehensive loss				
Unrealized gain (loss) on available-for-sale securities	(1)	25	(1)	(12)
Comprehensive loss	$(44,336)	$(77,807)	$(68,680)	$(150,709)

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 Shares	Amount	Additional Paid-in Capital	Receivables from the Exercises of Options	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
Balance at December 31, 2017	37,594,851	$ 4	$1,142,213	$ (449)	$ —	$(1,088,466)	$53,302
Stock-based compensation	—	—	47,536	—	—	—	47,536
Shares issued or restricted stock units vested under employee stock plans	295,369	—	5,851	290	—	—	6,141
Unrealized loss on available-for-sale securities					(1)		(1)
Net loss	—	—	—	—	—	(68,679)	(68,679)
Balance at June 30, 2018	37,890,220	$ 4	$1,195,600	$ (159)	$ (1)	$(1,157,145)	$38,299

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

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PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	For the Six Months Ended June 30,	
	2018	2017
Operating activities:		
Net loss	$(68,679)	$(150,697)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,224	551
Stock-based compensation	47,536	56,722
Debt modification fees	289	—
Changes in operating assets and liabilities:		
Accounts receivable, net	(11,673)	—
Inventory	(446)	—
Prepaid expenses and other	705	1,878
Accounts payable	(5,506)	4,479
Accrued expenses	10,543	5,148
Accrual of deferred rent	117	(35)
Net cash used in operating activities	(23,890)	(81,954)
Investing activities:		
Purchase of property and equipment	(245)	(132)
Restricted cash	—	1
Purchase of available-for-sale securities	(38,600)	(79,513)
Sale/maturity of available-for-sale securities	—	43,650
Net cash used in investing activities	(38,845)	(35,994)
Financing activities:		
Net proceeds from exercise of stock options	6,141	4,271
Proceeds from long-term debt	75,000	—
Payment of debt issuance costs	(4,192)	—
Net cash provided by financing activities	76,949	4,271
Net increase (decrease) in cash, cash equivalents and restricted cash	14,214	(113,677)
Cash, cash equivalents and restricted cash, beginning of period	86,015	198,811
Cash, cash equivalents and restricted cash, end of period	$100,229	$85,134
Supplemental disclosures of non-cash investing and financing activities:		
Property and equipment purchases in accounts payable	$150	$154
Receivables related to stock option exercises	$159	$—
Supplemental disclosure of cash flow information:		
Interest paid	$2,445	$—

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY

NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1—Business and Basis of Presentation:

Business:

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

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

Basis of Presentation:

The Company is focused on developing and commercializing neratinib for the treatment of patients with human epidermal growth factor receptor type 2, or HER2-positive, breast cancer, HER2 mutated non-small cell lung cancer, HER2-negative breast cancer that has a HER2 mutation and other solid tumors that have an activating mutation in HER2. The Company has reported a net loss of approximately $44.3 million and $68.7 million for the three and six months ended June 30, 2018, and negative cash flows from operations of approximately $23.9 million for the six months ended June 30, 2018. Management believes that the Company will continue to incur net losses and negative net cash flows from operating activities through the drug development process and global commercialization.

The Company has incurred significant operating losses and negative cash flows from operations since its inception, which raises substantial doubt about its ability to continue as a going concern. On July 17, 2017, the Company received U.S. Food and Drug Administration, or FDA, approval for its first product, NERLYNX® (neratinib), formerly known as PB272 (neratinib (oral)), for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer following adjuvant trastuzumab-based therapy. Following FDA approval in July 2017, NERLYNX became available by prescription in the United States, and the Company commenced commercialization. The Company entered into exclusive license agreements with Specialised Therapeutics Asia Pte Ltd., or STA, Medison Pharma Ltd., or Medison, and CANbridgepharma Limited, or CANbridge, and, most recently, Pint Pharma International SA, or Pint, to pursue regulatory approval and commercialize NERLYNX, if approved, in South East Asia, Israel, greater China and South America, respectively. The Company plans to continue to pursue commercialization of NERLYNX in other countries outside

the United States, if approved, and is evaluating various commercialization options in those countries, including developing a direct salesforce, contracting with third parties to provide sales and marketing capabilities, or some combination of these two options. On June 28, 2018, the Committee for Medicinal Products for Human Use, or CHMP, adopted a positive opinion, recommending marketing authorization for NERLYNX for the extended adjuvant treatment of adult patients with early stage hormone receptor positive HER2-overexpressed/amplified breast cancer and who are less than one year from the completion of prior adjuvant trastuzumab-based therapy. The CHMP recommendation will now be reviewed by the European Commission, which has the authority to approve medicines for the European Union. In addition, the Company is required to make substantial payments to Pfizer upon the achievement of certain milestones and has contractual obligations for clinical trial contracts.

Commercialization in the United States and, if approved, in the European Union, may require funding in addition to the cash and cash equivalents totaling approximately $95.9 million and marketable securities totaling approximately $38.6 million available at June 30, 2018. While the consolidated financial statements have been prepared on a going concern basis, the Company continues to remain dependent on its ability to obtain sufficient funding to sustain operations and successfully commercialize neratinib in the United States and, if approved, launch in the European Union. While the Company has been successful in raising capital in the past, there can be no assurance that it will be able to do so in the future. The Company’s ability to obtain funding may be adversely impacted by uncertain market conditions, unfavorable decisions of regulatory authorities or adverse clinical trial results. The outcome of these matters cannot be predicted at this time. The Company’s continued operations will depend on its ability to successfully commercialize NERLYNX, the Company’s only product approved by the FDA, and to obtain additional capital through various potential sources, such as equity and debt financing.

Since its inception through June 30, 2018, the Company's financing has primarily been through public offerings of Company common stock, private equity placements, borrowings under its loan and security agreement with Silicon Valley Bank, or SVB and Oxford Finance LLC, or Oxford, and licensing of its intellectual property.

The Company may need additional financing before it can achieve profitability, if ever. There can be no assurance that additional capital will be available on favorable terms or at all or that any additional capital that the Company is able to obtain will be sufficient to meet its needs. If it is unable to raise additional capital, the Company could likely be forced to curtail desired development activities, which will delay the development of its product candidates.

Note 2—Significant Accounting Policies:

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

Financial Instruments:

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

Use of Estimates:

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

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

Principles of Consolidation:

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

Investment Securities:

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

License Fees and Intangible Assets:

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

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

The Company assesses its intangible assets for impairment if indicators are present or changes in circumstance suggest that impairment may exist. Events that could result in an impairment, or trigger an interim impairment assessment, include the receipt of additional clinical or nonclinical data regarding one of the Company's drug candidates or a potentially competitive drug candidate, changes in the clinical development program for a drug candidate, or new information regarding potential sales of the drug. If impairment indicators are present or changes in circumstance suggest that impairment may exist, the Company performs a recoverability test by comparing the sum of the estimated undiscounted cash flows of each intangible asset to its carrying value on the consolidated balance sheet. If the undiscounted cash flows used in the recoverability test are less than the carrying value, the Company would determine the fair value of the intangible asset and recognize an impairment loss if the carrying value of the intangible asset exceeds its fair value. The FDA approval of NERLYNX in July 2017 triggered a one-time milestone payment pursuant to the Company's license agreement with the Pfizer. The Company capitalized the milestone payment as an intangible asset and is amortizing the asset to cost of sales on a straight-line basis through 2030, the estimated useful life of the licensed patent. The Company recorded amortization expense related to its intangible asset of $1.0 million and $2.0 million for the three and six months ended June 30, 2018, respectively. As of June 30, 2018, estimated future amortization expense related to the Company's intangible asset was approximately $1.9 million for the remainder of 2018, approximately $3.9 million for each year starting 2019 through 2029, and approximately $1.0 million for 2030.

Royalties:

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

Inventory:

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

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

As of June 30, 2018, the Company's inventory balance consisted primarily of raw materials purchased subsequent to FDA approval of NERLYNX.

Revenue Recognition:

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

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

Product Revenue, Net:

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

The Company recognizes revenue on product sales when the specialty pharmacy or specialty distributor, as applicable, obtains control of the Company's product, which occurs at a point in time (upon delivery). Product revenue is recorded net of applicable reserves for variable consideration, including discounts and allowances. The Company’s payment terms range between 10 and 68 days.

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

If taxes should be collected from these customers relating to product sales and remitted to governmental authorities, they will be excluded from revenue. The Company expenses incremental costs of obtaining a contract when incurred, if the expected amortization period of the asset that the Company would have recognized is one year or less. However, no such costs were incurred during the three months ended June 30, 2018.

Product revenue from customers who individually accounted for 10% or more of the Company’s total revenue for the three months ended June 30, 2018 consisted of the following, shown as a percentage of total revenue:

	Three Months

	Ended June 30, 2018	
Customer A	41	%
Customer B	25	%
Customer C	14	%

License Revenue:

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

Prior to recognizing revenue, the Company makes estimates of the transaction price, including variable consideration that is subject to a constraint. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur and when the uncertainty associated with the variable consideration is subsequently resolved. Variable consideration may include nonrefundable upfront license fees, payments for research and development activities, reimbursement of certain third-party costs, payments based upon the achievement of specified milestones, and royalty payments based on product sales derived from the collaboration.

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

During the first quarter of 2018, the Company entered into sub-licensing agreements with CANbridge and Medison, to pursue regulatory approval and commercialize NERLYNX, if approved, in the People's Republic of China (including mainland China, Hong Kong, Macao, and Taiwan) and Israel, respectively. The license agreements granted intellectual property rights and set forth the parties' respective obligations with respect to development, commercialization and supply of the licensed product. For both license agreements, non-refundable, upfront license fees were received and recognized as license revenue in accordance with ASC 606. Each respective license agreement met the contract existence criteria and contained distinct, identifiable performance obligations for which the stand-alone selling prices were readily determinable and allocable. The Company is obligated to supply both CANBridge and Medison with the licensed product in accordance with the respective supply agreements. These supply arrangements have been identified as separate performance obligations. The Company also identified the Joint Steering Committee as a separate, distinct performance obligation. To determine the respective stand-alone selling prices, the Company estimated the transaction prices, including any variable consideration, at contract inception and determined the fair value of such obligations based on similar arrangements. When determining the transaction prices, the Company assumed that the goods or services will be transferred to the customer based on the terms of the existing contract, and did not take into consideration the possibility of a contract being canceled, renewed, or modified. The Company noted there was no additional variable consideration, significant financing components, noncash consideration, or consideration payable to the customer in these agreements. These license agreements also include potential future milestone and royalty payments due to the Company upon successful completion of certain separate, distinct performance obligations.

Additionally, during the first quarter of 2018, the Company entered into a sub-license agreement with Pint. The license agreement granted intellectual property rights and set forth the respective obligations with respect to development, commercialization and supply of NERYLNX in 22 countries and territories in Central and South America. This license agreement met the contract existence criteria and contained distinct, identifiable performance obligations for which the stand-alone selling prices were readily determinable and allocable. Under the terms of the license agreement, the Company is entitled to receive a non-deductible, non-creditable upfront payment. Prior to receipt of such payment, the Company must provide certain required documents on or before September 30, 2018 to the satisfaction of Pint. As of June 30, 2018 the Company had not satisfied this performance obligation and no revenue has been recognized under the terms of the arrangement. The Company is obligated to supply Pint with the licensed product during development pursuant to a supply agreement. This supply arrangement has been identified as a separate performance obligation. To determine the respective stand-alone selling prices, the Company estimated the transaction prices, including any variable consideration, at contract inception and determined the fair value of such obligations based on similar arrangements. When determining the transaction prices, the Company assumed that the goods or services will be transferred to the customer based on the terms of the existing contract, and did not take into consideration the possibility of a contract being canceled, renewed, or modified. The Company noted there was no additional variable consideration, significant financing components, noncash consideration, or consideration payable to the customer in these agreements. This license agreement also includes potential future milestone and royalty payments due to the Company upon successful completion of certain separate, distinct events, such as achieving regulatory approvals. The non-deductible, non-creditable upfront payment and milestones consist of certain development and commercial performance obligations, and the Company could earn up to approximately $34.5

million if all respective performance obligations and milestones are achieved. At this time, the Company cannot estimate when these milestone-related performance obligations are expected to be achieved. The period between when we transfer control of the promised goods to a customer and when we receive payment from such customer is expected to be one year or less.

Reserves for Variable Consideration:

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

The amount of variable consideration that is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. The Company's analyses also contemplated application of the constraint in accordance with the guidance, under which it determined a material reversal of revenue would not occur in a future period for the estimates detailed below as of June 30, 2018 and, therefore, the transaction price was not reduced further during the quarter ended June 30, 2018. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Trade Discounts and Allowances:

The Company generally provides customers with discounts, which include incentive fees that are explicitly stated in the Company's contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized. The reserve for discounts is established in the same period that the related revenue is recognized, together with reductions to trade receivables, net on the consolidated balance sheets. In addition, the Company compensates its customers for sales order management, data, and distribution services. However, the Company has determined such services received to date are not distinct from the Company's sale of products to its customers and, therefore, these payments have been recorded as a reduction of revenue within the statement of operations and comprehensive loss through June 30, 2018.

Product Returns:

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

Provider Chargebacks and Discounts:

Chargebacks for fees and discounts to providers represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to its customers who directly purchase the product from the Company. Customers charge the Company for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. The reserve for chargebacks is established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider by customers, and the Company generally issues payments for such amounts within a few weeks of the customer's notification to the Company of the resale. Reserves for chargebacks consist of payments that the Company expects to issue for units that remain in the distribution channel at each

reporting period-end that the Company expects will be sold to qualified healthcare providers, and chargebacks that customers have claimed, but for which the Company has not yet issued a payment.

Government Rebates:

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

Payor Rebates:

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

Other Incentives:

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

Assets Measured at Fair Value on a Recurring Basis:

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

Level 1:	Quoted prices in active markets for identical assets or liabilities.
Level 2:	Quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs are observable in active markets.
Level 3:	Valuations derived from valuation techniques in which one or more significant inputs are unobservable.

Following are the major categories of assets measured at fair value on a recurring basis as of June 30, 2018 and December 31, 2017, using quoted prices in active markets for identical assets (Level 1), significant other observable inputs (Level 2), and significant unobservable inputs (Level 3) (in thousands):

June 30, 2018	Level 1	Level 2	Level 3	Total
Cash equivalents	$53,203	$20,443	$ —	$73,646
Commercial paper	—	32,786	—	32,786
Corporate bonds		5,814		5,814
	$53,203	$59,043	$ —	$112,246

December 31, 2017	Level 1	Level 2	Level 3	Total
Cash equivalents	$67,753	$—	$ —	$67,753
	$67,753	$—	$ —	$67,753

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 cash equivalents balance previously disclosed in the footnotes of the Company's 2017 Annual Report on form 10-K of $81.7 million incorrectly included cash of $13.9 million. The Company has excluded cash from the $67.8 million cash equivalents balance as of December 31, 2017 as currently presented. The misstatement was not material to the previously-reported financial statements.

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

June 30, 2018	Maturity (in years)	Amortized cost	Unrealized Gains	Unrealized Losses	Estimated fair value
Cash equivalents		$ 73,646	$ —	$ —	$ 73,646
Commercial paper	Less than 1	32,786	—	—	32,786
Corporate bonds	Less than 1	5,815	—	(1)	5,814
		$ 112,247	$ —	$ (1)	$ 112,246

December 31, 2017	Maturity (in years)	Amortized cost	Unrealized Gains	Unrealized Losses	Estimated fair value
Cash equivalents		$ 67,753	$ —	$ —	$ 67,753
		$ 67,753	$ —	$ —	$ 67,753

Concentration of Risk:

Financial instruments, which potentially subject the Company to concentrations of credit risk, principally consist of cash and cash equivalents and accounts receivable. The Company's cash and cash equivalents and restricted cash in excess of the Federal Deposit Insurance Corporation and the Securities Investor Protection Corporation insured limits at June 30, 2018, were approximately $100.7 million. The Company does not believe it is exposed to any significant credit risk due to the quality nature of the financial instruments in which the money is held. Pursuant to the Company's internal investment policy, investments must be rated A-1/P-1 or better by Standard and Poor's Rating Service and Moody's Investors Service at the time of purchase.

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

The Company's success depends on its ability to successfully commercialize NERLYNX. The Company currently has a single product with limited commercial sales experience, which makes it difficult to evaluate its current business,

predict its future prospects and forecast financial performance and growth. The Company has invested a significant portion of its efforts and financial resources in the development and commercialization of the lead product, NERLYNX, and expects NERLYNX to constitute the vast majority of product revenue for the foreseeable future. The Company's success depends on its ability to effectively commercialize NERLYNX.

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

Research and Development Expenses:

Research and development expenses, or R&D, are charged to operations as incurred. The major components of research and development expenses include clinical manufacturing costs, clinical trial expenses, consulting and other third-party costs, salaries and employee benefits, stock-based compensation expense, supplies and materials, and allocations of various overhead costs. Clinical trial expenses include, but are not limited to, investigator fees, site costs, comparator drug costs, and clinical research organization, or CRO, costs. In the normal course of business, the Company contracts with third parties to perform various clinical trial activities in the

ongoing development of potential products. The financial terms of these agreements are subject to negotiation and variations from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients and the completion of portions of the clinical trial or similar conditions. The Company's accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial sites, cooperative groups and CROs. The objective of the Company's accrual policy is to match the recording of expenses in the unaudited condensed consolidated financial statements to the actual services received and efforts expended. As actual costs become known, the Company adjusts its accruals in that period.

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

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

Stock-Based Compensation:

Stock Option Awards:

ASC 718, Compensation-Stock Compensation, or ASC 718, requires the fair value of all stock-based payments to employees, including grants of stock options, to be recognized in the statement of operations over the requisite service period. Under ASC 718, employee option grants are generally valued at the grant date and those valuations do not change once they have been established. The fair value of each option award is estimated on the grant date using the Black-Scholes Option Pricing Method. As allowed by ASC 718, the Company's estimate of expected volatility is based on its average volatilities using its past six years of publicly traded stock history. Prior to 2018, while the Company had a short period of publicly traded stock history, the Company calculated its estimate of average volatility based on a sampling of companies with similar attributes, including industry, stage of life cycle, size and financial leverage. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant valuation. Option forfeitures are calculated when the option is granted to reduce the option expense to be recognized over the life of the award and updated upon receipt of further information as to the amount of options expected to be forfeited. The option expense is "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:

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

Income Taxes:

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

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

On December 22, 2017, H.R. 1/Public Law No. 115-97 known as the Tax Cuts and Jobs Act, or the Tax Act, was signed into law. The effects of this new federal legislation are recognized upon enactment, which is the date a bill is signed into law. The Tax Act includes numerous changes in existing tax law, including a permanent reduction in the federal corporate income tax rate from 35% (as

the top corporate tax rate) to 21%. As a result of the Tax Act, the Company has revalued its net deferred tax assets as of December 31, 2017 to reflect the rate reduction. Tax rates used for the ASC 740 interim reporting reflect the newly enacted corporate tax rate of 21% and adjustments used for the estimated annual effective tax rate calculation reflect changes from the Tax Act.

Pursuant to the SEC Staff Accounting Bulletin No. 118, "Income Tax Accounting Implications of the Tax Cuts and Jobs Act," or SAB 118, a company may select between one of three scenarios to determine a reasonable estimate arising from the Tax Act. Those scenarios are (i) a final estimate which effectively closes the measurement window; (ii) a reasonable estimate leaving the measurement window open for future revisions; and (iii) no estimate as the law is still being analyzed. The Company was able to provide a reasonable estimate for the revaluation of deferred taxes by recording a net tax provision of $141.1 million in the period ending December 31, 2017, which is offset by a full valuation allowance. Other impacts of the Tax Act including, but not limited to, a limitation of the deduction for net operating losses, expensing of qualified property and additional limitations on the deductibility of executive compensation are not expected to have a material impact to the financial statement presentation or disclosures. The Company's review of the final impact of the Tax Act may be different from certain provisional amounts reported due to changes in interpretations and assumptions of the current guidance available as well as the issuance of new regulatory guidance in the future. As of June 30, 2018, the Company has not made any measurement period adjustments related to SAB 118, which was elected during the fourth quarter of 2017. The other income tax accounting implications resulting from the Tax Act do not have a material impact to the Company. The Company anticipates the full financial impact will be determined at the time its 2017 U.S. corporate income tax return is filed in 2018.

Segment Reporting:

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

Net Loss per Common Share:

Basic net loss per common share is computed by dividing net loss applicable to common stockholders by the weighted average number of common shares outstanding during the periods presented, as required by ASC 260, Earnings per Share. For purposes of calculating diluted loss per common share, the denominator includes both the weighted average number of common shares outstanding and the number of dilutive common stock equivalents, such as stock options, RSUs and warrants. A common stock equivalent is not included in the denominator when calculating diluted earnings per common share if the effect of such common stock equivalent would be anti-dilutive. For the three and six months ended June 30, 2018, potentially dilutive securities excluded from the calculations were 5,919,688 shares issuable upon exercise of options, 2,116,250 shares issuable upon exercise of a warrant, and 1,652,141 shares underlying RSUs that were subject to vesting and were antidilutive. For the three and six months ended June 30, 2017, potentially dilutive securities excluded from the calculations were 6,662,753 shares issuable upon exercise of options,

2,116,250 shares issuable upon exercise of a warrant, and 669,862 shares underlying RSUs that were subject to vesting and were antidilutive.

Recently Issued Accounting Standards:

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

In February 2016, the FASB issued ASU No. 2016-02, Leases. The amendments in ASU 2016-02 will require organizations that lease assets, with lease terms of more than 12 months, to recognize on their balance sheet the assets and liabilities for the rights and obligations created by those leases. Consistent with current GAAP, the recognition, measurement, and presentation of expenses and cash flows arising from a lease by a lessee primarily will depend on its classification as a finance or operating lease. However, unlike current GAAP which requires only capital leases to be recognized on the balance sheet, ASU No. 2016-02 will require both types of leases to be

recognized on the balance sheet. ASU 2016-02 will be effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. The Company is currently in the process of evaluating the impact of ASU 2016-02 on the Company's outstanding leases and expects that adoption will materially increase our assets and liabilities on the consolidated balance sheets related to recording right-of-use assets and corresponding lease liabilities.

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

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

Note 3—Prepaid Expenses and Other:

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

	June 30, 2018	December 31, 2017
Current:		
CRO services	$6,548	$ 7,188
Other clinical development	1,023	878
Insurance	632	1,306
Other	3,527	3,625
	11,730	12,997
Long-term:		
CRO services	1,382	860
Other clinical development	1,054	886
Insurance	34	26
Other	81	217
	2,551	1,989
Totals	$14,281	$ 14,986

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

Note 4—Property and Equipment:

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

	June 30, 2018	December 31, 2017
Property and Equipment:		
Leasehold improvements	$4,093	$ 3,878
Computer equipment	2,293	2,147
Telephone equipment	302	302
Furniture and fixtures	2,237	2,206
	8,925	8,533
Less: accumulated depreciation and amortization	(4,614)	(4,063)
Totals	$4,311	$ 4,470

Note 5—Intangible assets, net:

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

	June 30, 2018	Estimated useful life
Acquired and in-licensed rights	$50,000	13 Years
Less: accumulated amortization	(3,618)	
Total intangible asset, net	$46,382	

Note 6—Accrued Expenses:

Accrued expenses consisted of the following (in thousands):

	June 30, 2018	December 31, 2017
Accrued CRO services	8,337	$ 8,335
Accrued other clinical development	3,683	3,438
Accrued legal fees	3,617	2,046
Accrued compensation	4,263	2,797
Accrued bonus	4,218	3,376
Accrued royalties	7,615	3,922
Accrued variable consideration	4,863	1,425
Other	4,598	5,309
Totals	$41,194	$ 30,648

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

Note 7—Debt:

Long term debt consisted of the following at June 30, 2018 (dollars in thousands):

	June 30, 2018	Maturity Date
Long term debt	$125,000	May 1, 2023
Less: deferred financing costs	(4,731)	
Total long term debt, net	$120,269	

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On October 31, 2017, the Company entered into a loan and security agreement with SVB, as administrative agent, and the lenders party thereto from time to time, including Oxford and SVB. Pursuant to the terms of the credit facility provided for by the loan and security agreement, the Company borrowed $50.0 million.

On May 8, 2018, or the Amendment Date, the Company entered into the first amendment to the loan and security agreement. Under the amended credit facility, the lenders agreed to make term loans available to the Company in an aggregate amount of $155.0 million, consisting of (i) an aggregate amount of $125.0 million available on the Amendment Date, the proceeds of which, in part, were used to repay the $50.0 million borrowed under the original credit facility, and (ii) an aggregate amount of $30.0 million available to be drawn at the Company's option between September 30, 2018 and December 31, 2018, provided the Company has achieved a specified minimum revenue milestone and no event of default is occurring. Proceeds from the term loans under the amended credit facility may be used for working capital and general business purposes. Upon entry into the amended credit facility, the Company was required to pay the lenders aggregate fees of $4.2 million, consisting of a first amendment facility fee of $0.4 million and a final payment of $3.8 million in connection with the repayment of the $50.0 million borrowed under the original credit facility. The amended credit facility is secured by substantially all of the Company's personal property other than its intellectual property. The Company also pledged 65% of the issued and outstanding capital stock of its subsidiary, Puma Biotechnology Ltd.

The term loans under the amended credit facility bear interest at an annual rate equal to the greater of (i) 8.25% and (ii) the sum of (a) the "prime rate," as reported in The Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 3.5%. The Company is required to make monthly interest-only payments on each term loan commencing on the first calendar day of the calendar month following the funding date of such term loan, and continuing on the first calendar day of each calendar month thereafter through July 1, 2020. Commencing on July 1, 2020, and continuing on the first calendar day of each calendar month thereafter, the Company will make consecutive equal monthly payments of principal, together with applicable interest, in arrears to each lender, calculated pursuant to the amended credit facility. All unpaid principal and accrued and unpaid interest with respect to each term loan is due and payable in full on May 1, 2023. Upon repayment of the term loans, the Company is also required to make a final payment to the lenders equal to 7.5% of the original principal amount of term loans funded.

At the Company's option, the Company may prepay the outstanding principal balance of any term loan in whole but not in part, subject to a prepayment fee of 3.0% of any amount prepaid if the prepayment occurs through and including the first anniversary of the funding date of such term loan, 2.0% of any amount prepaid if the prepayment occurs after the first anniversary of the funding date of such term loan through and including the second anniversary of the funding date of such term loan, and 1.0% of the amount prepaid if the prepayment occurs after the second anniversary of the funding date of such term loan and prior to May 1, 2023.

The amended credit facility includes affirmative and negative covenants applicable to the Company, its current subsidiary and any subsidiaries the Company creates in the future. The affirmative covenants include, among others, covenants requiring the Company to maintain its legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and satisfy certain requirements regarding deposit accounts. The Company 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 Company's revenue target set forth in its board-approved projections for the 2018 fiscal year and (ii) greater than or equal to 50% of the Company's revenue target set forth in its board-approved projections for the 2019 fiscal year. New minimum revenue levels will be established for each subsequent fiscal year by mutual agreement of the Company, SVB as administrative agent, and the lenders. The negative covenants include, among others, restrictions on the Company's transferring collateral, incurring additional indebtedness, engaging in

mergers or acquisitions, paying dividends or making other distributions, making investments, creating liens, selling assets and suffering a change in control, in each case subject to certain exceptions.

The amended credit facility also includes events of default, the occurrence and continuation of which could cause interest to be charged at the rate that is otherwise applicable plus 5.0% and would provide SVB, as collateral agent, with the right to exercise remedies against the Company and the collateral securing the amended credit facility, including foreclosure against the property securing the credit facilities, including its cash. These events of default include, among other things, the Company's failure to pay principal or interest due under the amended credit facility, a breach of certain covenants under the amended credit facility, the Company's insolvency, a material adverse change, the occurrence of any default under certain other indebtedness in an amount greater than $0.5 million and one or more judgments against the Company in an amount greater than $0.5 million individually or in the aggregate.

On the Amendment Date, the Company issued to SVB and Oxford, as the sole lenders on the Amendment Date, secured promissory notes in an aggregate principal amount of $125.0 million evidencing the amended credit facility.

Note 8—Stockholders' Equity:

Stock Options and Restricted Stock Units:

The Company's 2011 Incentive Award Plan, as amended, or the 2011 Plan, was adopted by the Company's board of directors on September 15, 2011. Pursuant to the 2011 Plan, the Company may grant incentive stock options and nonqualified stock options, as well as other forms of equity-based compensation. Incentive stock options may be granted only to employees, while consultants, employees, officers and directors are eligible for the grant of nonqualified options under the 2011 Plan. The maximum term of stock options granted under the 2011 Plan is 10 years. The exercise price of incentive stock options granted under the 2011 Plan must be at least equal to the fair value of such shares on the date of grant. Through June 30, 2018, a total of 12,529,412 shares of the Company's common stock had been reserved for issuance under the 2011 Plan. As of June 30, 2018, 7,284,579 shares of the Company's common stock are issuable upon the vesting of RSU awards or exercise of outstanding awards granted under the 2011 Plan. As of June 30, 2018, 2,598,739 shares of the Company's common stock are available for future issuance under the 2011 Plan.

The Company's 2017 Employment Inducement Incentive Award Plan, or the 2017 Plan, was adopted by the Company's board of directors on April 27, 2017. Pursuant to the 2017 Plan, the Company may grant stock options and RSUs, as well as other forms of equity-based compensation to employees, as an inducement to join the Company. The maximum term of stock options granted under the 2017 Plan is 10 years. The exercise price of stock options granted under the 2017 Plan must be at least equal to the fair market value of such shares on the date of grant. As of June 30, 2018, a total of 1,000,000 shares of the Company's common stock had been reserved for issuance under the 2017 Plan. As of June 30, 2018, 287,250 shares of the Company's common stock are issuable upon the vesting of RSU awards granted under the 2017 Plan. As of June 30, 2018, 712,750 shares of the Company's common stock are available for future issuance under the 2017 Plan.

Stock-based compensation was as follows for the three and six months ended June 30 (in thousands except per share data):

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2018	2017	2018	2017
Stock-based compensation:				
Options -				
Research and development	$7,229	$17,886	$17,301	$38,237
Selling, general and administrative	4,118	6,365	8,589	12,554

Restricted stock units - Selling, general and administrative	4,454	985	8,949	2,080
Research and development	6,383	1,727	12,697	3,851
Total stock-based compensation expense	$22,184	$26,963	$47,536	$56,722

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 six months ended June 30, 2018 and 2017.

	2018	2017
Dividend yield	0.0 %	0.0 %
Expected volatility	95.5%	70.2%
Risk-free interest rate	2.5 %	2.0 %
Expected life in years	5.85	5.83

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

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2017	6,134,513	$ 87.91	7.2	$ 220,060
Granted	225,566	$ 73.40	9.6	
Forfeited	(130,641)	$ 54.64		
Exercised	(162,706)	$ 35.96		$ 4,546
Expired	(147,044)	$ 121.77		
Outstanding at June 30, 2018	5,919,688	$ 88.68	6.7	$ 72,371
Nonvested at June 30, 2018	1,160,293	$ 53.00	8.5	$ 15,004

At June 30, 2018, total estimated unrecognized employee compensation cost related to non-vested stock options granted prior to that date was approximately $34.3 million, which is expected to be recognized over a weighted-average period of 1.5 years. At June 30, 2018, the total estimated unrecognized employee compensation cost related to non-vested RSUs was approximately $105.3 million, which is expected to be recognized over a weighted-average period of 2.2 years. The weighted-average grant date fair value of options granted during the six months ended June 30, 2018 and 2017 was $56.46 and $24.30 per share, respectively. The weighted average grant date fair value of RSUs awarded during the six months ended June 30, 2018 was $65.80. No RSUs were awarded prior to June 30, 2017.

Stock options	Shares	Weighted Average Grant-Date Fair Value
Nonvested shares at December 31, 2017	1,788,436	$ 33.37
Granted	225,566	$ 56.46
Vested/Issued	(723,068)	$ 38.95
Forfeited	(130,641)	$ 32.95
Nonvested shares at June 30, 2018	1,160,293	$ 34.42

Weighted Average

Restricted stock units	Shares	Grant-Date Fair Value
Nonvested shares at December 31, 2017	1,637,662	$ 85.58
Granted	307,195	$ 65.80
Vested/Issued	(136,022)	$ 58.07
Forfeited	(156,694)	$ 85.43
Nonvested shares at June 30, 2018	1,652,141	$ 84.18

Note 9—401(k) Savings Plan:

During 2012, the Company adopted a 401(k) savings plan for the benefit of its employees. The Company is required to make matching contributions to the 401(k) plan equal to 100% of the first 3% of wages deferred by each participating employee and 50% on the next 2% of wages deferred by each participating employee. The Company incurred expenses for employer matching contributions of approximately $0.9 million and $0.4 million for the six months ended June 30, 2018 and 2017, respectively.

Note 10—Commitments and Contingencies:

Contractual Obligations:

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

Legal Proceedings

The Company and certain of its executive officers were named as defendants in the lawsuits detailed below. Due to the stage of these proceedings, the Company cannot reasonably predict the outcome, nor can it estimate the amount of loss or range of loss, if any, that may result. The Company records a liability in the consolidated financial statements for loss contingencies when a loss is known or considered probable and the amount can be reasonably estimated. If the reasonable estimate of a known or probable loss is a range, and no amount within the range is a better estimate than any other, the minimum amount of the range is accrued. If a loss is reasonably possible but not known or probable, and can be reasonably estimated, the estimated loss or range of loss is disclosed. When determining the estimated loss or range of loss, significant judgment is required to estimate the amount and timing of a loss to be recorded. An adverse outcome in these proceedings would likely not have a material adverse effect on the Company's results of operations, cash flows or financial condition.

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

On June 3, 2015, Hsingching Hsu individually and on behalf of all others similarly situated, filed a class action lawsuit against the Company and certain of the Company's executive officers in the United States District Court for the Central District of California (Case No. 8:15-cv-00865-AG-JCG). On October 16, 2015, lead plaintiff Norfolk Pension Fund filed a consolidated complaint on behalf of all persons who purchased the Company's securities between July 22, 2014 and May 29, 2015. The consolidated complaint alleges that the Company and certain of its executive officers made false or misleading statements and failed to disclose material adverse facts about its business, operations, prospects and performance in violation of Sections 10(b) (and Rule 10b-5 promulgated thereunder) and 20(a) of the Exchange Act. The plaintiff seeks damages, interest, costs, attorneys' fees, and other unspecified equitable relief. On July 10, 2018, the Company and two of its executive officers filed a motion for summary judgment seeking judgment in their favor on all claims. At the same time, the lead plaintiff filed its own motion for summary judgment, seeking judgment in favor on some, but not all, of its claims. The motions are scheduled for a hearing in court in September 2018. Pending those motions, a trial date is currently set for November 6, 2018. The Company intends to vigorously defend against this matter.

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

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

Derivative Actions

On April 12 and April 14, 2016, purported stockholders of the Company filed two derivative lawsuits purportedly on behalf of the Company against certain of the Company's officers and directors in the Superior Court of the State of California, Los Angeles, captioned Xing Xie v. Alan H. Auerbach, No. BC616617, and Kevin McKenney v. Auerbach, No. BC617059. The complaints asserted 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.

Separately, on February 9, 2018, another purported stockholder filed a derivative lawsuit purportedly on behalf of the Company against certain of its officers and directors in the United States District Court, Central District of California, captioned Arnaud Van Der Gracht De Rommerswael vs. Alan H. Auerbach, et al., No. 8:18-cv-00236. The complaint asserted claims for violation of securities law, breach of fiduciary duty, waste of corporate assets, and unjust enrichment arising from substantially similar allegations as those contained in the securities class action described above.

On May 30, 2018, another purported stockholder filed a derivative lawsuit purportedly on behalf of the Company against certain of its officers and directors in the United States District Court, Central District of California, captions Paul Duran vs. Alan H. Auerbach, et al., No. 2:18-cv-04802. The complaint asserted claims for violations of securities law, breach of fiduciary duties, unjust enrichment, abuse of control, gross mismanagement, and waste of corporate assets.

On July 30, 2018, the parties reached a settlement in principle of the Xie, Rommerswael and Duran lawsuits, and they intend to submit the final settlement agreement for court approval. The Company expects any amounts due as part of the settlement will be covered by the Company's insurance policies.

Note 11—Subsequent Events:

On July 30, 2018, the parties reached a settlement in principle of the Xie, Rommerswael and Duran lawsuits, and they intend to submit the final settlement agreement for court approval. The Company expects any amounts due as part of the settlement will be covered by the Company's insurance policies.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and the notes thereto included in Item 1 in this Quarterly Report on Form 10-Q. The following discussion should also be read in conjunction with our audited consolidated financial statements and the notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K for the year ended December 31, 2017.

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

Overview

We are a biopharmaceutical company with a focus on the development and commercialization of innovative products to enhance cancer care. We in-license the global development and commercialization rights to three drug candidates—PB272 (neratinib (oral)), PB272 (neratinib (intravenous)) and PB357. Neratinib is a potent irreversible tyrosine kinase inhibitor, or TKI, that blocks signal transduction through the epidermal growth factor receptors, HER1, HER2 and HER4. Currently, we are primarily focused on the development and commercialization of the oral version of neratinib, and our most advanced drug candidates are directed at the treatment of HER2-positive breast cancer. We believe neratinib has clinical application in the treatment of several other cancers as well, including non-small cell lung cancer and other tumor types that over-express or have a mutation in HER2. Prior to 2017, our efforts and resources had been focused primarily on acquiring and developing our pharmaceutical technologies, raising capital and recruiting personnel. During 2017, the United States Food and Drug Administration, or FDA, approved NERLYNX (neratinib), formally known as PB272 (neratinib (oral)), for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer following adjuvant trastuzumab-based therapy. Before we can market neratinib in countries outside the United States, we must receive regulatory approval from the appropriate government entities in those countries. Developing drug products is a lengthy and very expensive process.

We completed a Phase III clinical trial of neratinib for the extended adjuvant treatment of patients with early stage HER2-positive breast cancer, which we refer to as the ExteNET trial. Based on the results from the ExteNET trial, we submitted a Marketing Authorization Application, or MAA, with the European Medicines Agency, or EMA, in June 2016. Following the adoption of a negative opinion and the recommended refusal by the EMA's Committee for Medicinal Products for Human Use, or CHMP, of our MAA for neratinib for the extended adjuvant treatment of early-stage HER2 positive breast cancer, we requested a re-examination of the same. On June 28, 2018, the CHMP adopted a positive opinion, recommending marketing authorization for NERLYNX for the extended adjuvant treatment of adult patients with early stage hormone receptor positive HER2-overexpressed/amplified breast cancer and who are less than one year from the completion of prior adjuvant trastuzumab-based therapy. The CHMP recommendation will now be reviewed by the European Commission, which has the authority to approved medicines for the European Union.

We have entered into exclusive license agreements with Specialised Therapeutics Asia Pte Ltd., Medison Pharma Ltd., CANbridgepharma Limited and, Pint Pharma International SA to pursue regulatory approval and commercialize NERLYNX, if approved, in South East Asia, Israel, greater China and Latin America, respectively. We plan to continue to pursue commercialization of NERLYNX in other countries outside the United States, if approved, and will evaluate various commercialization options in those countries, including developing a direct salesforce, contracting with third parties to provide sales and marketing capabilities, or some combination of these two options. We expect that our expenses will continue to increase as we continue commercialization efforts.

Our license agreement with Pfizer, Inc., or Pfizer, for PB272 established a limit for our expenses related to the Pfizer-initiated clinical trials for PB272 that were ongoing at the time of the agreement. This capped our "out-of-pocket" costs incurred in conducting these existing trials beginning January 1, 2012. We reached the cost cap during the fourth quarter of 2012, which resulted in a reduction of our research and development, or R&D, expenses for the fourth quarter of 2012 and for the year ended December 31, 2013. In July 2014, we signed an amendment to the license agreement with Pfizer whereby we would be responsible for the expenses incurred or accrued in conducting the ongoing legacy clinical trials after December 31, 2013. Additionally, our expenses to date have been related to hiring staff, commencing company-sponsored clinical trials and the build out of our corporate infrastructure. As we proceed with clinical development of PB272 (neratinib (oral)), and as we further develop PB272 (neratinib (intravenous)), and PB357, our second and third product candidates, respectively, we expect our clinical R&D expenses and expenses related to our third-party contractors associated with clinical operations will begin to decline unless we decide to pursue additional clinical trials in alternate indications or acquire additional product candidates.

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

Critical Accounting Policies

As of the date of the filing of this Quarterly Report, we believe there have been no material changes to our critical accounting policies and estimates during the three months ended June 30, 2018 from our accounting policies at December 31, 2017, as reported in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, with the exception of the sub-license agreements listed below:

License Revenue:

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

Prior to recognizing revenue, we make estimates of the transaction price, including variable consideration that is subject to a constraint. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur and when the uncertainty associated with the variable consideration is subsequently resolved. Variable consideration may include nonrefundable upfront license fees, payments for research and development activities, reimbursement of certain third-party costs, payments based upon the achievement of specified milestones, and royalty payments based on product sales derived from the collaboration.

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

During the first quarter of 2018, we entered into sub-license agreements with CANbridge and Medison, to pursue regulatory approval and commercialize NERLYNX, if approved, in the People’s Republic of China (including mainland China, Hong Kong, Macao, and Taiwan) and Israel, respectively. The license agreements granted

intellectual property rights and set forth the parties' respective obligations with respect to development, commercialization and supply of the licensed product. For both license agreements, non-refundable, upfront license fees were received and recognized as license revenue in accordance with ASC 606. Each respective license agreement met the contract existence criteria and contained distinct, identifiable performance obligations for which the stand-alone selling prices were readily determinable and allocable. We are obligated to supply both CANBridge and Medison with the licensed product in accordance with the respective supply agreements. These supply arrangements have been identified as separate performance obligations. We also identified the Joint Steering Committee as a separate, distinct performance obligation. To determine the respective stand-alone selling prices, we estimated the transaction prices, including any variable consideration, at contract inception and determined the fair value of such obligations based on similar arrangements. When determining the transaction prices, we assumed that the goods or services will be transferred to the customer based on the terms of the existing contract, and did not take into consideration the possibility of a contract being canceled, renewed, or modified. We noted there was no additional variable consideration, significant financing components, noncash consideration, or consideration payable to the customer in these agreements. These license agreements also include potential future milestone and royalty payments due to us upon successful completion of certain separate, distinct performance obligations.

Additionally, during the first quarter of 2018, we entered into a sub-license agreement with Pint Pharma International SA (Pint), or Pint. The license agreement granted intellectual property rights and set forth the respective obligations with respect to development, commercialization and supply of NERYLNX in 22 countries and territories in Central and South America. This license agreement met the contract existence criteria and contained distinct, identifiable performance obligations for which the stand-alone selling prices were readily determinable and allocable. Under the terms of the license agreement, we are entitled to receive a non-deductible, non-creditable upfront payment. Prior to receipt of such payment, we must provide certain required documents on or before September 30, 2018 to the satisfaction of Pint. At June 30, 2018 we had not satisfied this performance obligation and no revenue has been recognized under the terms of the arrangement. We are obligated to supply Pint with the licensed product during development pursuant to a supply agreement. This supply arrangement has been identified as a separate performance obligation. To determine the respective stand-alone selling prices, we estimated the transaction prices, including any variable consideration, at

contract inception and determined the fair value of such obligations based on similar arrangements. When determining the transaction prices, we assumed that the goods or services will be transferred to the customer based on the terms of the existing contract, and did not take into consideration the possibility of a contract being canceled, renewed, or modified. We noted there was no additional variable consideration, significant financing components, noncash consideration, or consideration payable to the customer in these agreements. This license agreement also includes potential future milestone and royalty payments due to us upon successful completion of certain separate, distinct events, such as achieving regulatory approvals. The non-deductible, non-creditable upfront payment and milestones consist of certain development and commercial performance obligations, and we could earn up to approximately $34.5 million if all respective performance obligations are achieved. At this time, we cannot estimate when these milestone-related performance obligations are expected to be achieved. The period between when we transfer control of the promised goods to a customer and when we receive payment from such customer is expected to be one year or less.

Summary of Income and Expenses

Product revenue, net:

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

License revenue:

License revenue consists of consideration paid to us pursuant to our license agreements.

Cost of sales:

Cost of sales consists of third-party manufacturing costs, freight, and indirect overhead costs associated with sales of NERLYNX. Cost of product sales also includes period costs related to royalty charges payable to Pfizer, the amortization of a milestone payment made to the Licensor after obtaining FDA approval of NERLYNX, certain inventory manufacturing services, inventory adjustment charges, unabsorbed manufacturing and overhead costs, and manufacturing variances.

Selling, general and administration expenses:

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

We expect SG&A expenses in 2018 and into 2019 to remain higher than in 2017 as we launch NERLYNX commercially in the United States and beyond. Our evaluation of the means by which to launch in Europe is ongoing and remains to be determined once approval is received, if ever. The majority of the salesforce and field based support personnel were hired in the late third quarter of 2017 and we expect a full year's worth of salesforce expenses in 2018. We expect this increase should be partially offset by an expected reduction in legal fees and system implementation fees.

Research and development expenses:

R&D expenses include costs associated with services provided by consultants who conduct clinical services on our behalf, contract organizations for manufacturing of clinical materials and clinical trials. During the six months ended June 30, 2018 and 2017, our R&D expenses consisted primarily of clinical research organization, or CRO, fees; fees paid to consultants; salaries and related personnel costs; and stock-based compensation. We expense our R&D costs as they are incurred. Internal expenses primarily consist of payroll-related costs, but also include equipment costs, travel expenses and supplies. External expenses primarily consist of clinical trial expenses and consultant and contractor expense, and also include costs such as legal fees, insurance costs and manufacturing expense.

We expect R&D expenses in 2018 to continue to decline slightly when compared with R&D expenses in 2017 based on a decline in clinical trial activities as existing trials continue to wind down.

Results of Operations

Three Months Ended June 30, 2018 Compared to Three Months Ended June 30, 2017

Product revenue, net:

Product revenue, net was approximately $50.8 million for the three months ended June 30, 2018, compared to $0 for the three months ended June 30, 2017. The increase in product revenue, net was entirely attributable to sales of NERLYNX, which had its commercial launch in July 2017.

Cost of sales:

For the three months ended June 30, 2018, cost of sales was approximately $8.8 million compared to $0 for the three months ended June 30, 2017. The increase in cost of sales was entirely attributable to the commercial launch of NERLYNX in July 2017.

Selling, general and administrative expenses:

For the three months ended June 30, 2018, SG&A expenses were approximately $40.1 million, compared to approximately $24.9 million for the three months ended June 30, 2017. SG&A expenses for the three months ended June 30, 2018 and 2017 were as follows:

	For the Three Months		Change		
Selling, general and administrative expenses (in thousands)	Ended June 30, 2018	2017	$ 2018/2017	% 2018/2017	
External	$14,534	$12,580	$1,954	15.5	%
Internal	17,029	4,999	12,030	240.6	%
Employee stock-based compensation expense	8,572	7,350	1,222	16.6	%
	$40,135	$24,929	$15,206	61.0	%

For the three months ended June 30, 2018, SG&A expenses increased by approximately $15.2 million compared to the same period in 2017, and was primarily attributable to the following:

- an increase of approximately $12.0 million in internal expenses, comprised of increases of approximately $10.0 million due to the addition of a salesforce to support the commercial launch of NERLYNX, approximately $1.3 million in marketing and market access related expenses, approximately $0.5 million in payroll and other internal SG&A functions and approximate $0.2 million in rent expense;

- an increase in external expenses of approximately $2.0 million, comprised of increases of approximately $6.5 million for marketing and commercialization support and approximately $0.3 million to support our commercialization strategy in Europe, partially offset by decreases of approximately $2.1 million in spending on IT infrastructure implementations, approximately $1.8 million from preparation for the U.S. commercial launch of NERLYNX and approximately $1.0 million in other expenses such as legal fees; and

- an increase of approximately $1.2 million in employee stock-based compensation expense associated with additional headcount, primarily in support of the commercial launch of NERLYNX.

Research and development expenses:

For the three months ended June 30, 2018, R&D expenses were approximately $43.2 million, compared to approximately $53.3 million for the three months ended June 30, 2017. R&D expenses for the three months ended June 30, 2018 and 2017 were as follows:

	For the Three Months Ended June 30,		Change	
Research and development expenses (in thousands)	2018	2017	$ 2018/2017	% 2018/2017
External	$18,652	$23,697	$(5,045)	(21.3%)
Internal	10,981	9,943	1,038	10.4%
Employee stock-based compensation	13,612	19,613	(6,001)	(30.6%)
	$43,245	$53,253	$(10,008)	(18.8%)

For the three months ended June 30, 2018, R&D expenses decreased approximately $10.0 million compared to the same period in 2017, primarily attributable to the following:

- a decrease in external expenses of approximately $6.4 million due to a reduction in CRO related expenses for our clinical trials;
- a decrease of approximately $6.0 million in employee stock-based compensation;
- an increase of approximately $1.4 million in external R&D costs, primarily from additional medical affairs activity including support of the CHMP re-assessment; and
- an increase of approximately $1.0 million in internal R&D costs, primarily for additional personnel needed to support medical affairs and quality assurance.

Interest income:

For the three months ended June 30, 2018, we recognized approximately $0.3 million in interest income compared to approximately $0.4 million of interest income for the three months ended June 30, 2017. The decrease in interest income reflects less cash in money market accounts and “high yield” savings accounts in 2018 compared to 2017.

Other expenses:

During the three months ended June 30, 2018, other expenses consisted primarily of costs related to a settlement of legal matters and fees from the modification of debt.

Interest expense:

For the three months ended June 30, 2018, we recognized approximately $2.6 million in interest expense, compared to $0 of interest expense for the three months ended June 30, 2017. This increase in interest expense is a result of the debt financing that closed in October 2017 (see Note 7 in the notes to the accompanying unaudited condensed consolidated financial statements).

Six Months Ended June 30, 2018 Compared to Six Months Ended June 30, 2017

Total revenue:

For the six months ended June 30, 2018, total revenue was approximately $117.3 million, compared to $0 for the six months ended June 30, 2017.

Product revenue, net:

Product revenue, net was approximately $86.8 million for the six months ended June 30, 2018, compared to $0 for the six months ended June 30, 2017. The increase in product revenue, net was entirely attributable to sales of NERLYNX, which had its commercial launch in July 2017.

License revenue:

License revenue was $30.5 million for the six months ended June 30, 2018, compared to $0 for the six months ended June 30, 2017. The increase in license revenue was entirely attributable to upfront payments associated with two license agreements that were entered into during the six months ended June 30, 2018.

Cost of sales:

For the six months ended June 30, 2018, cost of sales was approximately $15.2 million compared to $0 for the six months ended June 30, 2017. The increase in cost of sales was entirely attributable to the commercial launch of NERLYNX in July 2017.

Selling, general and administrative expenses:

For the six months ended June 30, 2018, SG&A expenses were approximately $76.7 million, compared to approximately $43.3 million for the six months ended June 30, 2017. SG&A expenses for the six months ended June 30, 2018 and 2017 were as follows:

	For the Six Months Ended June 30,		Change		
Selling, general and administrative expenses (in thousands)	2018	2017	$ 2018/2017	% 2018/2017	
External	$27,791	$19,242	$8,549	44.4	%
Internal	31,408	9,454	21,954	232.2	%
Employee stock-based compensation expense	17,538	14,634	2,904	19.8	%
	$76,737	$43,330	$33,407	77.1	%

For the six months ended June 30, 2018, SG&A expenses increased by approximately $33.4 million compared to the same period in 2017. The approximate $33.4 million increase in SG&A expenses for the six months ended June 30, 2018, was primarily attributable to the following:

- an increase of approximately $22.0 million in internal SG&A expenses due primarily to increases of approximately $18.5 million from the addition of a salesforce to support the commercial launch of NERLYNX, approximately $2.1 million in marketing and market access related expenses, approximately $1.0 million in payroll and other SG&A expenses and approximately $0.3 million in rent expense;

- an increase in external expenses of approximately $8.5 million, comprised of increases of approximately $12.5 million for marketing and commercialization support, approximately $0.8 million to support our commercialization strategy in Europe, and approximately $0.6 million in other expenses such as audit fees and business licenses, partially offset by decreases of approximately $2.5 million from preparation for the U.S. commercial launch of NERLYNX in 2017, approximately $2.3 million in spending on IT infrastructure implementations, and approximately $0.5 million in legal fees; and

- an increase of approximately $2.9 million in employee stock-based compensation expense associated with additional headcount, primarily in support of the commercial launch of NERLYNX.

Research and development expenses:

For the six months ended June 30, 2018, R&D expenses were approximately $90.2 million, compared to approximately $108.1 million for the six months ended June 30, 2017. R&D expenses for the six months ended June 30, 2018 and 2017 were as follows:

Research and development expenses (in thousands)	For the Six Months Ended June 30, 2018	2017	Change $ 2018/2017	% 2018/2017
External	$37,309	$46,312	$(9,003)	(19.4%)
Internal	22,862	19,654	3,208	16.3%
Employee stock-based compensation	29,998	42,088	(12,090)	(28.7%)
	$90,169	$108,054	$(17,885)	(16.6%)

For the six months ended June 30, 2018, R&D expenses decreased approximately $17.9 million compared to the same period in 2017. The decrease of approximately $17.9 million is primarily attributable to the following:

- a decrease of approximately $12.1 million in employee stock-based compensation;
- a decrease in external expenses of approximately $9.0 million primarily due to a reduction in CRO related expenses for our clinical trials;
- an increase of approximately $3.2 million in internal R&D costs, primarily for additional personnel needed to support medical affairs and quality assurance; and
- an increase of approximately $0.1 million in external R&D costs driven by an increase of approximately $1.8 million in medical affairs and post-marketing support, offset by a decrease of approximately $1.7 million in comparator drug costs.

Interest income:

For the six months ended June 30, 2018, we recognized approximately $0.5 million in interest income compared to approximately $0.7 million for the six months ended June 30, 2017. The decrease in interest income reflects less income from marketable securities and less cash in money market accounts and “high yield” savings accounts in 2018 compared to 2017.

Other expenses:

During the six months ended June 30, 2018, other expenses, consisted primarily of settlement costs of legal matters and fees from the modification of debt.

Interest expense:

For the six months ended June 30, 2018, we recognized approximately $3.7 million in interest expense, compared to $0 of interest expense for the six months ended June 30, 2017. This increase in interest expense is a result of the debt financing that closed in October 2017 (see Note 7 in the notes to the accompanying unaudited condensed consolidated financial statements).

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of June 30, 2018 and December 31, 2017, and for the six months ended June 30, 2018 and 2017, and is intended to supplement the more detailed discussion that follows:

Liquidity and capital resources (in thousands)	June 30, 2018	December 31, 2017
Cash and cash equivalents	$95,912	$ 81,698
Marketable securities	$38,600	$ —
Working capital	$106,530	$ 48,054
Stockholders' equity	38,299	53,302

	Six Months Ended June 30, 2018	Six Months Ended June 30, 2017
Cash provided by (used in):		
Operating activities	$(23,890)	$ (81,954)
Investing activities	(38,845)	(35,994)
Financing activities	76,949	4,271
Decrease in cash and cash equivalents	$14,214	$ (113,677)

Operating Activities:

For the three and six months ended June 30, 2018, we reported a net loss of approximately $44.3 million and $68.7 million, compared to approximately $77.8 million and $150.7 million for the same periods in 2017, respectively. Additionally, cash used in operating activities for the three and six months ended June 30, 2018 was approximately $17.6 million and $23.9 million, compared to approximately $45.9 million and $82.0 million for the same periods in 2017, respectively.

Cash used in operating activities for the six months ended June 30, 2018 consisted of a net loss of approximately $68.7 million, an increase in net accounts receivable of approximately $11.7 million, an increase of approximately $10.5 million in accrued expenses and an increase of approximately $0.4 million in inventory, offset by a decrease of approximately $5.5 million in accounts payable, a $0.7 decrease in prepaid expenses and other and $51.0 million of non-cash items such as stock-based compensation, depreciation and amortization, and loss on modification of debt.

Cash used in operating activities for the six months ended June 30, 2017 consisted of a net loss of $150.7 million, offset by approximately $57.3 million of non-cash items such as depreciation and amortization and stock-based compensation, an increase of approximately $9.6 million in accrued expenses and accounts payable and an increase of approximately $1.9 million in prepaid expenses and other.

Investing Activities:

During the six months ended June 30, 2018, net cash used in investing activities was approximately $38.8 million, compared to approximately $36.0 million for the same period in 2017. Net cash used in investing activities during the six months ended June 30, 2018 was made up of approximately $38.6 million of cash invested in available-for-sale securities and $0.2 million of cash used to purchase property and equipment. Net cash used in investing activities during the six months ended June 30, 2017 was made up of approximately $43.7 million of sales or maturities of available-for-sale securities, offset by $79.5 million of cash invested in available-for-sale securities, and approximately $0.1 million used to purchase property and equipment.

Financing Activities:

During the six months ended June 30, 2018, cash provided by financing activities was approximately $76.9 million, which consisted of approximately $75.0 million of incremental proceeds from the our amended credit facility with SVB, and $6.1 million of net proceeds from the exercise of stock options, partially offset by $4.2 million of cash used for the payment of debt issuance costs relating to our amended credit facility with SVB. During the same period in 2017, cash provided by financing activities was approximately $4.3 million, comprised of net proceeds from the exercise of stock options.

Loan and Security Agreement:

On October 31, 2017, we entered into a loan and security agreement with SVB, as administrative agent, and the lenders party thereto from time to time, including Oxford Finance LLC, or Oxford, and SVB. Pursuant to the terms of the credit facility provided for by the loan and security agreement, we borrowed $50 million.

On May 8, 2018, or the Amendment Date, we entered into a first amendment to the loan and security agreement. Under the amended credit facility, the lenders agreed to make term loans available to us in an aggregate amount of $155 million, consisting of (i) an aggregate amount of $125 million available on the Amendment Date, the proceeds of which, in part, were used to repay the $50 million we borrowed under the original credit facility, and (ii) an aggregate amount of $30 million available to be drawn at our option between September 30, 2018 and December 31, 2018 provided that we have achieved a specified minimum revenue milestone and no event of default is occurring. Proceeds from the term loans under the amended credit facility may be used for working capital and general business purposes. Upon the entry into the amended credit facility, we were required to pay the lenders aggregate fees of $4,162,500, consisting of a first amendment facility fee of $412,500 and a final payment of $3,750,000 in connection with the repayment of the $50 million borrowed under the original credit facility. The amended credit facility is secured by substantially all of our personal property other than our intellectual property. We also pledged 65% of the issued and outstanding capital stock of our subsidiary, Puma Biotechnology Ltd.

The term loans under the amended credit facility bear interest at an annual rate equal to the greater of (i) 8.25% and (ii) the sum of (a) the "prime rate," as reported in The Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 3.5%. We are required to make monthly interest-only payments on each term loan commencing on the first calendar day of the calendar month following the funding date of such term loan, and continuing on the first calendar day of each calendar month thereafter through July 1, 2020. Commencing on July 1, 2020, and continuing on the first calendar day of each calendar month thereafter, we will make consecutive equal monthly payments of principal, together with applicable interest, in arrears to each lender, calculated pursuant to the amended credit facility. All unpaid principal and accrued and unpaid interest with respect to each term loan is due and payable in full on May 1, 2023. Upon repayment of the term loans, we are also required to make a final payment to the lenders equal to 7.5% of the original principal amount of term loans funded.

At our option, we may prepay the outstanding principal balance of any term loan in whole but not in part, subject to a prepayment fee of 3.0% of any amount prepaid if the prepayment occurs through and including the first anniversary of the funding date of such term loan, 2.0% of any amount prepaid if the prepayment occurs after the first anniversary of the funding date of such term loan through and including the second anniversary of the funding date of such term loan, and 1.0% of the amount prepaid if the prepayment occurs after the second anniversary of the funding date of such term loan and prior to May 1, 2023.

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

The amended credit facility also includes events of default, the occurrence and continuation of which could cause interest to be charged at the rate that is otherwise applicable plus 5.0% and would provide SVB, as collateral agent, with the right to exercise remedies against us and the collateral securing the amended credit facility, including foreclosure against the property securing the credit facilities, including our cash. These events of default include,

among other things, a failure by us to pay principal or interest due under the amended credit facility, a breach of certain covenants under the amended credit facility, our insolvency, a material adverse change, the occurrence of any default under certain other indebtedness in an amount greater than $500,000 and one or more judgments against us in an amount greater than $500,000 individually or in the aggregate.

On the Amendment Date, the Company issued to SVB and Oxford, as the sole lenders on the Amendment Date, secured promissory notes in an aggregate principal amount of $125,000,000 evidencing the amended credit facility.

Current and Future Financing Needs:

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

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

We are currently exploring methods by which to commercialize our other product candidates if approved by the FDA or EMA. These methods may require funding in addition to the cash and cash equivalents totaling approximately $95.9 million and $38.6 million in marketable securities available at June 30, 2018. While our consolidated financial statements have been prepared on a going concern basis, we expect to continue incurring significant losses for the foreseeable future and will continue to remain dependent on our ability to obtain sufficient funding to sustain operations and successfully commercialize neratinib. While we have been successful in raising financing in the past, there can be no assurance that we will be able to do so in the future. Our ability to obtain funding may be adversely impacted by uncertain market conditions, unfavorable decisions of regulatory authorities or adverse clinical trial results. The outcome of these matters cannot be predicted at this time.

In addition, we have based our estimate of capital needs on assumptions that may prove to be wrong. Changes may occur that would consume our available capital faster than anticipated, including changes in and progress of our development activities, the impact of commercialization efforts, acquisitions of additional drug candidates and changes in regulation. Potential sources of financing include strategic relationships, public or private sales of equity or debt and other sources of funds. We may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. Although we may have access to an additional $30 million from our loan and security agreement with SVB during the fourth quarter of 2018, provided we have achieved a specified minimum revenue milestone and no event of default is occurring, it is uncertain whether additional funding will be available when we need it on terms that will be acceptable to us, or at all. If we raise funds by selling additional shares of common stock or other securities convertible into common stock, the ownership interests of our existing stockholders will be diluted. If we are not able to obtain financing when needed, we may be unable to carry out our business plan. As a result, we may have to significantly limit our operations, and our business, financial condition and results of operations would be materially harmed. In such an event, we will be required to undertake a thorough review of our programs, and the opportunities presented by such programs, and allocate our resources in the manner most prudent.

Going Concern:

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

Contractual Obligations:

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

Non-GAAP Financial Measures:

In addition to our operating results, as calculated in accordance with generally accepted accounting principles, or GAAP, we use certain non-GAAP financial measures when planning, monitoring, and evaluating our operational performance. The following table presents our net loss and net loss per share, as calculated in accordance with GAAP, as adjusted to remove the impact of stock-based compensation. For the three and six ended June 30, 2018, stock-based compensation represented approximately 50.0% and 69.2% of our net loss, respectively, and 34.6% and 43.1% for the same periods in 2017. Although net loss is important to measure our financial performance, we currently place an emphasis on cash burn and, more specifically, cash used in operations. Because stock-based compensation appears in GAAP net loss but is removed from net loss to arrive at cash used in operations on the statement of cash flows, due to its non-cash nature, we believe these non-GAAP measures enhance understanding of our financial performance, are more indicative of our operational performance and facilitate a better comparison among fiscal periods. These non-GAAP financial measures are not, and should not be viewed as, substitutes for GAAP reporting measures.

Reconciliation of GAAP Net Loss to Non-GAAP Adjusted Net 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 June 30,			For the Six Months Ended June 30,		
	2018	2017		2018	2017	
GAAP net loss	$(44,335)	$(77,832)		$(68,679)	$(150,697)	
Adjustments:						
Stock-based compensation - Selling, general and administrative	8,572	7,350	(1)	17,538	14,634	(1)
Research and development	13,612	19,613	(2)	29,998	42,088	(2)
Non-GAAP adjusted net loss	$(22,151)	$(50,869)		$(21,143)	$(93,975)	
GAAP net loss per share—basic	$(1.17)	$(2.10)		$(1.82)	$(4.08)	
Adjustment to net loss (as detailed above)	0.58	0.72		1.26	1.54	
Non-GAAP adjusted basic net loss per share	$(0.59)	$(1.38)	(3)	$(0.56)	$(2.54)	(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 basic net loss per share was calculated based on 37,819,767 and 36,992,017 weighted average common shares outstanding for the three months ended June 30, 2018 and 2017, respectively, and 37,759,729 and 36,961,760 weighted average common shares outstanding for the six months ended June 30, 2018 and 2017, 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

Some of the securities that we invest in have market risk in that a change in prevailing interest rates may cause the principal amount of the cash equivalents to fluctuate. Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash and cash equivalents. We invested our excess cash primarily in cash equivalents such as money market investments as of June 30, 2018. The primary objectives of our investment activities are to ensure liquidity and to preserve principal while at the same time maximizing the income we receive from our cash and cash equivalents without significantly increasing risk. Additionally, we established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity.

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

We also have interest rate exposure as a result of borrowings outstanding under our loan and security agreement with SVB. As of June 30, 2018, the outstanding principal amount of our borrowings was $125.0 million. Our borrowings under the loan and security agreement, as amended, bear interest at an annual rate equal to the greater of (i) 8.25% and (ii) the sum of (a) the "prime rate," as reported in The Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 3.5%. Changes in the prime rate may therefore affect our interest expense associated with our borrowings under the loan and security agreement.

Item 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

Under the supervision and with the participation of our management, including our Chief Executive Officer and Senior Vice President, Finance and Administration and Treasurer, we have evaluated the effectiveness of our disclosure controls and procedures (as defined under Exchange Act Rule 13a-15(e)), as of June 30, 2018. Based on that evaluation, our Chief Executive Officer and Senior Vice President, Finance and Administration and Treasurer have concluded that these disclosure controls and procedures were effective as of June 30, 2018.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the quarter ended June 30, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II – OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

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

On June 3, 2015, Hsingching Hsu or the "plaintiff," individually and on behalf of all others similarly situated, filed a class action lawsuit against us and certain of our executive officers in the United States District Court for the Central District of California (Case No. 8:15-cv-00865-AG-JCG). On October 16, 2015, lead plaintiff Norfolk Pension Fund filed a consolidated complaint on behalf of all persons who purchased our securities between July 22, 2014 and May 29, 2015. The consolidated complaint alleges that we and certain of our executive officers made false or misleading statements and failed to disclose material adverse facts about our business, operations, prospects and performance in violation of Sections 10(b) (and Rule 10b-5 promulgated thereunder) and 20(a) of the Exchange Act. The plaintiff seeks damages, interest, costs, attorneys' fees, and other unspecified equitable relief. On July 10, 2018, we and two of our executive officers filed a motion for summary judgment seeking judgment in our favor on all claims. At the same time, the lead plaintiff filed its own motion for summary judgment, seeking judgment in favor on some, but not all, of its claims. The motions are scheduled for a hearing in court in September 2018. Pending those motions, a trial date is currently set for November 6, 2018. We intend to vigorously defend against this matter.

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

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

Derivative Actions

On April 12 and April 14, 2016, purported stockholders filed two derivative lawsuits purportedly on behalf of us against certain of our officers and directors in the Superior Court of the State of California, Los Angeles, captioned Xing Xie vs. Alan H. Auerbach, No. BC616617, and Kevin McKenney vs. Auerbach, No. BC617059. The complaints asserted claims for breach of fiduciary duty, unjust enrichment, abuse of control, mismanagement and waste of corporate assets arising from substantially similar allegations as those contained in the Hsu securities class action

described above. The complaints seek an unspecified sum of damages and equitable relief.

Separately, on February 9, 2018, another purported stockholder filed a derivative lawsuit purportedly on behalf of us against certain of our officers and directors in the United States District Court, Central District of California, captions Arnaud Van Der Gracht De Rommerswael vs. Alan H. Auerbach, et al., No. 8:18-cv-00236. The complaint asserted claims for violation of securities law, breach of fiduciary duty, waste of corporate assets, and unjust enrichment arising from substantially similar allegations as those contained in the Hsu securities class action described above.

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

On July 30, 2018, the parties reached a settlement in principle of the Xie, Rommerswael and Duran lawsuits, and they intend to submit the final settlement agreement for court approval. We expect any amounts due as part of the settlement will be covered by our insurance policies.

Item 1A. RISK FACTORS

Under Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2017, which was filed with the SEC on March 9, 2018, we identified important factors that could affect our financial performance and could cause our actual results for future periods to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statements made in this Form 10-Q. There has been no material change in our risk factors subsequent to the filing of our Annual Report. However, the risks described in our Annual Report are not the only risks we face. Additional risks and uncertainties that we currently deem to be immaterial or not currently known to us, as well as other risks reported from time to time in our reports to the SEC, also could cause our actual results to differ materially from our anticipated results or other expectations.

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

Recent Sales of Unregistered Securities

We did not sell any of our equity securities without registration under the Securities Act of 1933, as amended, during the three months ended June 30, 2018.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Neither we nor any “affiliated purchasers” within the definition of Rule 10b-18(a)(3) promulgated under the Exchange Act made any purchases of our equity securities during the quarter ended June 30, 2018.

Item 3. DEFAULTS UPON SENIOR SECURITIES

None.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Item 5. OTHER INFORMATION

None.

Item 6. EXHIBITS

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

Exhibit	Description
3.1	Second Amended and Restated Certificate of Incorporation of the Company, as filed with the Secretary of State of the State of Delaware on June 14, 2016 (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on June 15, 2016 and incorporated herein by reference)
3.2	Second Amended and Restated Bylaws of the Company (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on May 8, 2017 and incorporated herein by reference)
10.1(a)*	First Amendment to Loan and Security Agreement, dated May 8, 2018, by and among the Company, Silicon Valley Bank, as administrative and collateral agent
10.1(b)*	Form of Secured Promissory Note (included as Exhibit D to Exhibit 10.1(a))
10.2*	Amendment No. 1, dated April 20, 2018, to the License Agreement by and between the Company and Specialised Therapeutics Asia Pte Ltd.
10.3*	Supply Agreement, dated April 20, 2018, by and between the Company and Specialised Therapeutics Asia Pte. Ltd.
10.4#	Amended Non-Employee Director Compensation Program
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, with respect to the registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018
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 June 30, 2018
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

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

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SIGNATURES

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

PUMA BIOTECHNOLOGY, INC.

Date: August 9, 2018	By:	/s/ Alan H. Auerbach Alan H. Auerbach President and Chief Executive Officer (Principal Executive Officer)
Date: August 9, 2018	By:	/s/ Charles R. Eyler Charles R. Eyler Senior Vice President, Finance and Administration and Treasurer (Principal Financial and Accounting Officer)

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