ANTARES PHARMA, INC.
Form 10-Q
August 08, 2017

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, 2017

Commission File Number 1-32302

ANTARES PHARMA, INC.

A Delaware Corporation IRS Employer Identification No. 41-1350192
100 Princeton South, Suite 300

Ewing, New Jersey 08628

(609) 359-3020

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

The number of shares outstanding of the registrant’s Common Stock, $.01 par value, as of August 1, 2017 was 156,407,319.

ANTARES PHARMA, INC.

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PART I – FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS
ANTARES PHARMA, INC.

CONSOLIDATED BALANCE SHEETS

	June 30, 2017 (Unaudited)	December 31, 2016
Assets		
Current Assets:		
Cash and cash equivalents	$33,418,393	$27,714,588
Short-term investments	9,960,479	—
Accounts receivable	9,067,689	9,073,173
Inventories	7,845,547	5,326,962
Deferred costs	893,619	1,773,446
Prepaid expenses and other current assets	1,690,036	1,376,299
Total current assets	62,875,763	45,264,468
Equipment, molds, furniture and fixtures, net	17,550,876	17,867,412
Patent rights, net	1,766,830	2,044,608
Goodwill	1,095,355	1,095,355
Other assets	53,847	53,607
Total Assets	$83,342,671	$66,325,450
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$8,478,038	$7,884,983
Accrued expenses and other liabilities	6,172,077	5,872,846
Deferred revenue	3,483,297	6,149,087
Total current liabilities	18,133,412	19,906,916
Long-term debt	24,724,304	—
Deferred revenue – long term	200,000	1,200,000
Total liabilities	43,057,716	21,106,916
Stockholders' Equity:		
Preferred Stock: $0.01 par, authorized 3,000,000 shares, none outstanding	—	—
Common Stock: $0.01 par; 300,000,000 shares authorized; 156,332,319 and 155,167,677 issued and outstanding at June 30, 2017 and December 31, 2016, respectively	1,563,323	1,551,677
Additional paid-in capital	300,537,059	297,826,433
Accumulated deficit	(261,118,353)	(253,445,306)
Accumulated other comprehensive loss	(697,074)	(714,270)
	40,284,955	45,218,534
Total Liabilities and Stockholders' Equity	$83,342,671	$66,325,450

See accompanying notes to consolidated financial statements.

ANTARES PHARMA, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2017	2016	2017	2016
Revenue:				
Product sales	$7,344,413	$8,690,002	$17,381,225	$19,531,049
Development revenue	4,787,672	3,267,397	6,409,549	4,365,771
Licensing revenue	1,019,040	38,721	1,037,718	89,422
Royalties	265,034	232,270	595,126	560,920
Total revenue	13,416,159	12,228,390	25,423,618	24,547,162
Cost of revenue:				
Cost of product sales	3,633,218	5,216,527	9,081,509	11,464,083
Cost of development revenue	1,983,171	2,101,571	2,754,646	2,629,756
Total cost of revenue	5,616,389	7,318,098	11,836,155	14,093,839
Gross profit	7,799,770	4,910,292	13,587,463	10,453,323
Operating expenses:				
Research and development	3,159,363	3,948,020	6,245,644	9,596,049
Selling, general and administrative	7,360,010	7,014,520	14,827,265	14,617,698
Total operating expenses	10,519,373	10,962,540	21,072,909	24,213,747
Operating loss	(2,719,603)	(6,052,248)	(7,485,446)	(13,760,424)
Other income (expense)	(120,341)	(9,215)	(90,415)	42,851
Net loss	$(2,839,944)	$(6,061,463)	$(7,575,861)	$(13,717,573)
Basic and diluted net loss per common share	$(0.02)	$(0.04)	$(0.05)	$(0.09)
Basic and diluted weighted average common shares outstanding	155,926,149	154,936,096	155,572,562	154,897,089

See accompanying notes to consolidated financial statements.

ANTARES PHARMA, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(UNAUDITED)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2017	2016	2017	2016
Net loss	$(2,839,944)	$(6,061,463)	$(7,575,861)	$(13,717,573)
Foreign currency translation adjustment	12,855	(5,755)	17,196	(10,452)
Comprehensive loss	$(2,827,089)	$(6,067,218)	$(7,558,665)	$(13,728,025)

See accompanying notes to consolidated financial statements.

ANTARES PHARMA, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	Six Months Ended June 30,	
	2017	2016
Cash flows from operating activities:		
Net loss	$(7,575,861)	$(13,717,573)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,283,592	1,277,277
Depreciation and amortization	971,489	891,388
Loss on disposal of equipment	—	17,785
Write-off of capitalized patent costs	45,600	—
Accretion of interest expense	13,980	—
Amortization of debt issuance costs	3,863	—
Amortization of premiums and discounts on investment securities	(133)	7,798
Changes in operating assets and liabilities:		
Accounts receivable	9,663	(2,358,302)
Inventories	(2,518,585)	(1,734,536)
Prepaid expenses and other assets	(309,507)	582,241
Deferred costs	879,827	(942,063)
Accounts payable	721,038	5,073,875
Accrued expenses and other current liabilities	48,877	369,693
Deferred revenue	(3,668,284)	1,849,291
Net cash used in operating activities	(10,094,441)	(8,683,126)
Cash flows from investing activities:		
Purchase of investment securities	(9,963,978)	—
Purchases of equipment, molds, furniture and fixtures	(529,239)	(2,555,174)
Additions to patent rights	(56,970)	(39,019)
Proceeds from maturities of investment securities	—	6,000,000
Net cash provided by (used in) investing activities	(10,550,187)	3,405,807
Cash flows from financing activities:		
Proceeds from issuance of long-term debt	25,000,000	—
Payment of debt issuance costs	(241,431)	—
Proceeds from exercise of stock options	1,590,204	—
Taxes paid related to net share settlement of equity awards	—	(64,096)
Net cash provided by (used in) financing activities	26,348,773	(64,096)
Effect of exchange rate changes on cash	(340)	1,947
Net increase (decrease) in cash	5,703,805	(5,339,468)
Cash and cash equivalents:		
Beginning of period	27,714,588	32,898,676
End of period	$33,418,393	$27,559,208
Supplemental disclosure of non-cash investing activities:		
Purchases of equipment, molds, furniture and fixtures recorded in accounts payable	$271,959	$1,293,346

and accrued expenses		
Additions to patent rights recorded in accounts payable and accrued expenses	$18,313	$32,586
Supplemental disclosure of non-cash financing activities:		
Tax witholding on net settled equity awards included in accrued liabilities	$248,709	$—
Debt issuance costs included in accounts payable and accrued expenses	$52,108	$—

See accompanying notes to consolidated financial statements.

ANTARES PHARMA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

1. Description of Business

Antares Pharma, Inc. ("Antares" or the "Company") is an emerging, specialty pharmaceutical company focused on the development and commercialization of self-administered parenteral pharmaceutical products and technologies. The Company develops and manufactures, for itself or with partners, novel therapeutic products using its advanced drug delivery technology to enhance the existing drug compounds and delivery methods. The subcutaneous injection technology platforms include the VIBEX® pressure-assisted auto injector system suitable for branded and generic injectable drugs in unit dose containers, reusable needle-free spring-action injector devices, and disposable multi-dose pen injectors for use with standard cartridges. The Company has a portfolio of proprietary and partnered products, including approved commercial products and several product candidates in advanced stages of development and under active review by the U.S. Food and Drug Administration ("FDA"). The Company has formed significant strategic alliances with Teva Pharmaceutical Industries, Ltd. ("Teva"), AMAG Pharmaceuticals, Inc. ("AMAG"), Ferring Pharmaceuticals Inc. and Ferring B.V. (together "Ferring").

The Company markets and sells its proprietary product OTREXUP® (methotrexate) injection in the U.S., which was launched in February 2014. OTREXUP® is the first subcutaneous methotrexate for once weekly self-administration with an easy-to-use, single dose, disposable auto injector approved by the FDA. OTREXUP® is indicated for adults with severe active rheumatoid arthritis ("RA"), children with active polyarticular juvenile idiopathic arthritis and adults with severe recalcitrant psoriasis.

The Company, with its commercialization partner Teva, launched Sumatriptan Injection USP, indicated in the U.S. for the acute treatment of migraine and cluster headache in adults, in June 2016. In December 2015, the Company received FDA approval for an Abbreviated New Drug Application ("ANDA") for 4 mg/0.5 mL and 6 mg/0.5 mL single-dose prefilled syringe auto-injectors, a generic equivalent to Imitrex® STATdose Pen®. Sumatriptan Injection USP represents the Company's first ANDA approval of a complex generic and second product approved using the VIBEX® auto injector platform.

The Company is developing XYOSTED™ (testosterone enanthate) injection for testosterone replacement therapy, and submitted a 505 (b) (2) New Drug Application ("NDA") to the FDA in December 2016. The NDA submission was accepted for standard review by the FDA and assigned a Prescription Drug User Fee Act ("PDUFA") target date for completion of its review by October 20, 2017. The Company also has multiple ongoing product development programs with its partners Teva and AMAG.

2. Basis of Presentation and Significant Accounting Policies

The accompanying unaudited consolidated financial statements have been prepared in accordance with generally accepted accounting principles ("GAAP") in the U.S. for interim financial information and with the instructions to Form

10-Q and Article 10 of the Securities and Exchange Commission's Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the U.S. for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. The accompanying consolidated financial statements and notes thereto should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended December 31, 2016. Operating results for the three and six months ended June 30, 2017 are not necessarily indicative of the results that may be expected for the year ending December 31, 2017.

Investments

The primary objectives of the Company's investment policy are to protect principal, maintain adequate liquidity and maximize returns. The Company's investments consist of U.S. Treasury bills and government agency notes that are classified as held-to-maturity because the Company has the intent and ability to hold the securities to maturity. Investments with maturities of one year or less are classified as short-term. The securities are carried at their amortized cost and the fair value is determined by quoted market prices. At June 30, 2017, the Company's investments had a carrying value of $9,960,479, which approximated fair value. The Company held no investments as of December 31, 2016.

Inventories

Inventories are stated at the lower of cost or net realizable value. Cost is determined on a first-in, first-out basis. Certain components of the Company's products are provided by a limited number of vendors, and the Company's production, assembly, warehousing and distribution operations are outsourced to third-parties where substantially all of the Company's inventory is located. Disruption of supply from key vendors or third-party suppliers may have a material adverse impact on the Company's

operations. The Company provides a reserve for potentially excess, dated or obsolete inventories based on an analysis of inventory on hand compared to forecasts of future sales, which was $750,000 and $900,000 at June 30, 2017 and December 31, 2016, respectively. Inventories consist of the following:

	June 30, 2017	December 31, 2016
Inventories:		
Raw material	$85,344	$ 142,491
Work in process	5,656,453	2,429,075
Finished goods	2,103,750	2,755,396
	$7,845,547	$ 5,326,962

OTREXUP® Revenue Recognition

The Company began detailing OTREXUP® to health care professionals in February 2014. OTREXUP® is sold in packages of four pre-filled, single-dose disposable auto injectors to wholesale pharmaceutical distributors, its customers, subject to rights of return within a period beginning six months prior to, and ending 12 months following, product expiration.

Prior to the first quarter of 2017, the Company could not reliably estimate expected returns of OTREXUP® at the time of shipment given its limited sales history of the product. Accordingly, the recognition of revenue was deferred on product shipments until the rights of return no longer existed, which occurred at the earlier of the time OTREXUP® units were dispensed through patient prescriptions or expiration of the right of return of the product. Patient prescriptions dispensed were estimated using third-party market prescription data.

In the first quarter of 2017, the Company determined it had developed sufficient historical information to reasonably estimate future returns of OTREXUP® and began recognizing revenue, net of estimated returns, upon delivery to the distributors. The Company recognized $8,487,163 in product sales for OTREXUP® for the six months ended June 30, 2017, which included $1,297,054 for product shipped to distributors in previous periods but not recognized as revenue at the time of shipment, net of the returns allowance established in the first quarter of 2017. The Company also recognized $254,425 of related product costs in the six months ended June 30, 2017 that had been previously deferred. The net impact of these changes resulted in a decrease in net loss of $1,042,629, less than $0.01 per share, for the six months ended June 30, 2017.

Product sales revenue for OTREXUP® is presented net of estimated returns and product sales allowances for wholesaler discounts, prompt pay discounts, chargebacks, rebates and patient discount programs. The estimated product returns reserve was $630,000 as of June 30, 2017 and zero at December 31, 2016. Product sales allowances were $2,081,476 as of June 30, 2017 and $1,540,488 as of December 31, 2016.

Product Sales Allowances

The Company recognizes product sales allowances as a reduction of product sales in the same period the related revenue is recognized. Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with customers and third-party payors and the levels of inventory within the distribution channels that may result in future rebates or discounts taken. In certain cases, such as patient support programs, the Company recognizes the cost of patient discounts as a reduction of

revenue based on estimated utilization. If actual future results vary, it may be necessary to adjust these estimates, which could have an effect on product revenue in the period of adjustment. Product sales allowances include:

Wholesaler Distribution Fees. Distribution fees are paid to certain wholesale distributors based on contractually determined rates. The Company accrues the fee on shipment to the respective wholesale distributors and recognizes the fee as a reduction of revenue in the same period the related revenue is recognized.

Prompt Pay Discounts. The Company offers cash discounts to its customers, generally 2% of the sales price, as an incentive for prompt payment. The Company accounts for cash discounts by reducing accounts receivable by the prompt pay discount amount and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.

Chargebacks. The Company provides discounts to authorized users of the Federal Supply Schedule (“FSS”) of the General Services Administration under an FSS contract negotiated by the Department of Veterans Affairs and various organizations under Medicaid contracts and regulations. These entities purchase products from the wholesale distributors at a discounted price, and the wholesale distributors then charge back to the Company the difference between the current wholesale acquisition cost and the price the entity paid for the product. The Company estimates and accrues chargebacks based on

estimated wholesaler inventory levels, current contract prices and historical chargeback activity. Chargebacks are recognized as a reduction of revenue in the same period the related revenue is recognized.

Rebates. The Company participates in certain rebate programs, which provide discounted prescriptions to qualified insured patients. Under these rebate programs, the Company will pay a rebate to the third-party administrator of the program, generally two to three months after the quarter in which prescriptions subject to the rebate are filled. The Company estimates and accrues for these rebates based on current contract prices, historical and estimated percentages of product sold to qualified patients. Rebates are recognized as a reduction of revenue in the same period the related revenue is recognized.

Patient Discount Programs. The Company offers discount card programs to patients for OTREXUP® in which patients receive discounts on their prescriptions that are reimbursed by the Company. The Company estimates the total amount that will be redeemed based on historical redemption experience and on estimated levels of inventory in the distribution and retail channels and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.

3. Long-Term Debt

On June 6, 2017, the Company entered into a loan and security agreement (the "Loan Agreement") with Hercules Capital, Inc., for a term loan of up to $35,000,000 (the "Term Loan"), the proceeds of which are to be used for working capital and general corporate purposes. The first advance of $25,000,000 was funded upon execution of the Loan Agreement on June 6, 2017. Under the terms of the Loan Agreement, the Company may, but is not obligated to, request one or more additional advances of at least $5,000,000 not to exceed $10,000,000 in the aggregate, subject to the Company achieving certain corporate milestones and satisfying customary conditions. The Company must exercise its option to request additional advances prior to September 30, 2018.

The Term Loan is secured by substantially all of the Company's assets, excluding intellectual property, and will mature on July 1, 2022. The Term Loan accrues interest at a calculated prime-based variable rate with a maximum interest rate of 9.50%. As of June 30, 2017, the interest rate was 8.75%. Payments under the Loan Agreement are interest only until the first principal payment is due on August 1, 2019, provided that the interest only period may be extended to February 1, 2020 if the Company achieves certain corporate milestones. The Loan Agreement also requires the Company to pay a fee equal to 4.25% of the total original principal amount of all term loan advances ("End of Term Charge"), which is due upon repayment of the Term Loan at either maturity or earlier repayment, and imposes a prepayment fee of 1.0% to 3.0% if any or all of the balance is prepaid prior to the maturity date.

As of June 30, 2017, the carrying value of the Term Loan was $24,724,304, which consisted of the $25,000,000 principal balance outstanding and the End of Term Charge accrual of $13,980, less unamortized debt issuance costs of $289,676. The Company incurred debt issuance costs that, along with the End of Term Charge, are being amortized/accrued to interest expense over the term of the Term Loan using the effective interest method.

Future principal payments under the term loan, including the End of Term Charge, are as follows:

	June 30, 2017
2017	$—
2018	—

2019	3,086,729
2020	7,883,810
2021	8,595,931
Thereafter	6,496,030
	$26,062,500

The Company believes that the carrying value of the Term Loan approximates its fair value based on the borrowing rates currently available for loans with similar terms.

4. Share-Based Compensation

The Company's 2008 Equity Compensation Plan (the "Plan") allows for grants in the form of incentive stock options, nonqualified stock options, stock units, stock awards, stock appreciation rights, and other stock-based awards. All of the Company's officers, directors, employees, consultants and advisors are eligible to receive grants under the Plan. The maximum number of shares authorized for issuance under the amended and restated Plan is 32,200,000 and the maximum number of shares of stock that may be granted to any one employee for qualified performance-based compensation during a calendar year

is 4,000,000 shares. Options to purchase shares of common stock are granted at exercise prices not less than 100% of fair market value on the dates of grant. The term of each option is ten years and the options typically vest in quarterly installments over a three-year period with a minimum vesting period of one year. As of June 30, 2017, the Plan had approximately 6,500,000 shares available for grant. Stock option exercises are satisfied through the issuance of new shares.

Stock Options

The following is a summary of stock option activity under the Plan as of and for the six months ended June 30, 2017:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2016	11,313,909	$ 1.84		
Granted	2,803,667	2.65		
Exercised	(969,108)	1.64		
Cancelled/Forfeited	(674,619)	2.49		
Outstanding at June 30, 2017	12,473,849	2.01	7.4	$15,597,050
Exercisable at June 30, 2017	7,614,437	$ 1.94	6.2	$10,232,347

The per share weighted average fair values of all options granted during the six months ended June 30, 2017 and 2016 were estimated as $1.37 and $0.54, respectively, on the date of grant using the Black-Scholes option pricing model based on the assumptions noted in the table below. Expected volatilities are based on the historical volatility of the Company's stock price. The weighted average expected life is based on both historical and anticipated employee behavior.

	June 30, 2017	2016
Risk-free interest rate	1.8%	1.3%
Annualized volatility	53.4%	51.6%
Weighted average expected life, in years	6.0	6.0
Expected dividend yield	0.0%	0.0%

During the six months ended June 30, 2017, stock option exercises resulted in cash proceeds to the Company of $1,590,204 and the issuance of 969,108 shares of common stock. No stock options were exercised during the six months ended June 30, 2016.

The Company recognized $987,603 and $1,067,047 of compensation expense related to stock options for the six months ended June 30, 2017 and 2016, respectively, and $520,161 and $504,814 for the three months ended June 30,

2017 and 2016, respectively. As of June 30, 2017, there was approximately $4,900,000 of total unrecognized compensation cost related to non-vested outstanding stock options that is expected to be recognized over a weighted average period of approximately 2.2 years.

Long Term Incentive Program

The Company's Board of Directors has approved a long term incentive program ("LTIP") for the benefit of the Company's senior executives. Pursuant to the LTIP, the Company's senior executives have been awarded stock options, restricted stock units ("RSU") and performance stock units ("PSU") with targeted values based on values granted to similarly situated senior executives in the Company's peer group.

The stock options have a ten-year term, have an exercise price equal to the closing price of the Company's common stock on the date of grant, vest in quarterly installments over three years, were otherwise granted on the same standard terms and conditions as other stock options granted pursuant to the Plan and are included in the stock options table above. The RSUs vest in three equal annual installments. The PSU awards made to the senior executives vest and convert into shares of the Company's common stock based on the Company's attainment of certain performance goals as established by the Company's Board of Directors over a performance period, which is typically three to five years.

The performance stock unit awards and restricted stock unit awards granted under the long-term incentive program are summarized in the following table:

	Performance Stock Units		Restricted Stock Units	
	Number of Shares	Weighted Average Grant Date Fair Value	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2016	1,347,289	$ 1.50	822,658	$ 1.39
Granted	649,180	2.81	649,180	2.66
Vested/settled	—		(287,508)	1.49
Forfeited/expired	(502,308)	2.16	(67,464)	1.70
Outstanding at June 30, 2017	1,494,161	$ 2.04	1,116,866	$ 2.08

In 2017, 2016 and 2015, the LTIP awards include PSUs that may be earned based on the Company's total shareholder return ("TSR") relative to the Nasdaq Biotechnology Index ("NBI") at the end of the performance period. The performance period is January 1, 2015 to December 31, 2017 for the 2015 award, January 1, 2016 to December 31, 2018 for the 2016 award and January 1, 2017 to December 31, 2019 for the 2017 award. Depending on the outcome of the performance goal, a recipient may ultimately earn a number of shares greater or less than their target number of shares granted, ranging from 0% to 150% of the PSUs granted. The fair values of the TSR PSUs granted was determined using a Monte Carlo simulation and utilized the following inputs and assumptions:

	2017 Award	2016 Award	2015 Award
Closing stock price on grant date	$ 2.66	$ 1.12	$ 2.18
Performance period starting price	$ 2.17	$ 1.29	$ 2.52
Term of award (in years)	2.57	2.58	2.59
Volatility	54.6 %	70.1 %	60.5 %
Risk-free interest rate	1.39 %	0.97 %	0.83 %
Expected dividend yield	0.00 %	0.00 %	0.00 %
Fair value per TSR PSU	$ 3.10	$ 1.25	$ 1.71

The performance period starting price is measured as the average closing price over the last 20 trading days prior to the performance period start. The Monte Carlo simulation model also assumed correlations of returns of the prices of the Company's common stock and the common stocks of the NBI companies and stock price volatilities of the NBI companies. The fair value of the target number of shares that can be earned under the TSR PSUs is being recognized as compensation expense over the performance period.

In connection with PSU awards, the Company recognized compensation expense of $88,296 and $8,294 for the six months ended June 30, 2017 and 2016, respectively. Compensation expense recognized in connection with RSU awards was $207,693 and $201,936 for the six months ended June 30, 2017 and 2016, respectively.

Shares issued in connection with LTIP awards that vested in the six months ended June 30, 2017 and 2016 were net-share settled such that the Company withheld shares with a value equivalent to the employees' minimum statutory obligation for the applicable income and other employment taxes, and remitted the cash to the appropriate taxing authorities. The total shares withheld to satisfy tax obligations were 97,586 and 65,575 in the six months ended June 30, 2017 and 2016, respectively, and were based on the fair value of the shares on their vesting date as determined by the Company's closing stock price. Total payments for the employees' tax obligations to the taxing authorities were $248,709 and $64,096 in the six months ended June 30, 2017 and 2016, respectively, and are reflected as a financing activity within the consolidated statements of cash flows. These net-share settlements had the effect of share repurchases by the Company as they reduced the number of shares that would have otherwise been issued as a result of the vesting and did not represent an expense to the Company.

5. Significant Customers and Concentrations of Risk

Revenues by customer location are summarized as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
United States of America	$12,167,166	$11,024,136	$22,835,189	$21,594,742
Europe	1,112,185	1,047,250	2,267,629	2,614,591
Other	136,808	157,004	320,800	337,829
	$13,416,159	$12,228,390	$25,423,618	$24,547,162

Significant customers from which the Company derived 10% or more of total revenue are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Teva	$4,417,179	$6,505,126	$9,380,253	$12,990,976
AMAG	3,803,460	410,919	4,570,573	905,882
McKesson	1,769,827	1,846,255	3,993,842	3,555,549
Ferring	987,103	1,055,767	2,294,597	2,714,389
AmerisourceBergen	1,444,397	1,354,801	2,852,745	2,501,887

6. Net Loss Per Share

Basic loss per common share is computed by dividing net loss applicable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted loss per common share reflects the potential dilution from the exercise or conversion of securities into common stock. Potentially dilutive stock options and other share-based awards excluded from dilutive loss per share because their effect was anti-dilutive totaled 15,084,876 and 15,017,289 at June 30, 2017 and 2016, respectively.

7. Recent Accounting Pronouncements

Accounting Pronouncements Recently Adopted

In July 2015, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2015-11, Simplifying the Measurement of Inventory. The new standard changed the measurement principle for inventory from the lower of cost or market to lower of cost and net realizable value. The Company adopted this standard during the first quarter of 2017, and the adoption did not have an impact on the consolidated results of

operations, cash flows or financial position of the Company.

In March 2016, the FASB issued ASU No. 2016-09, Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting ("ASU 2016-09"). The new standard involves several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. The Company adopted ASU 2016-09 effective January 1, 2017, and the adoption did not have a significant impact on the Company's consolidated financial statements. As required under previous GAAP, the Company had estimated forfeitures in determining its periodic compensation costs related to share-based awards. Upon adoption of the new standard, the Company has elected to recognize forfeitures as they occur, and recorded a cumulative effect adjustment to accumulated deficit and additional paid-in capital of $97,000, the net of which had no impact on the Company's consolidated results of operations, cash flows or financial position.

In January 2017, the FASB issued ASU 2017-04, Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment ("ASU 2017-04"). This new standard eliminates Step 2 from the goodwill impairment test. ASU 2017-04 requires an entity to perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value. ASU 2017-04 still allows the option to perform a qualitative assessment for a reporting unit to determine if the quantitative impairment test is necessary. The Company early adopted this standard effective January 1, 2017 and will apply the standard prospectively for its annual goodwill impairment tests. The adoption of the standard did not have an impact on the Company's consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers ("ASU No. 2014-09"). This guidance requires an entity to recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard creates a five-step model that requires a company to identify customer contracts, identify the separate performance obligations, determine the transaction price, allocate the transaction price to the separate performance obligations and recognize revenue when each performance obligation is satisfied. This guidance also requires an entity to disclose sufficient information to enable users of financial statements to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. Qualitative and quantitative information is required about contract balances and remaining performance obligations, significant judgments made in determining the timing of satisfaction of performance obligations (over time or at a point in time), and estimates made in determining the transaction price and amounts allocated to performance obligations.

The Company continues to monitor and evaluate the impact the adoption of this standard will have on its consolidated financial statements and has performed an initial review of its major contracts with customers. Based on the initial reviews, the Company believes the adoption of the new standard may accelerate the timing of revenue recognition for product sales and development revenue under certain license, development and supply agreements, and will require management to estimate and potentially recognize certain variable revenue streams such as royalties and profit sharing arrangements earlier at an amount it believes will not be subject to significant reversal.

The Company anticipates adopting the new revenue recognition standard on the effective date of January 1, 2018 utilizing the modified retrospective method of adoption, under which the cumulative effect of the change is recognized as an adjustment to the opening balance of the accumulated deficit within the consolidated balance sheet, and prior reporting periods are not retrospectively adjusted. No significant changes to business processes or systems are currently expected to be necessary.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) ("ASU 2016-02"). This new standard requires entities to recognize on its balance sheet assets and liabilities associated with the rights and obligations created by leases with terms greater than twelve months. This new standard is effective for annual reporting periods beginning after December 15, 2018, and interim periods within those annual periods and early adoption is permitted. The Company is currently evaluating the impact of ASU 2016-02 on its consolidated financial statements and currently expects that most of its operating lease commitments will be subject to the new standard and recognized as operating lease liabilities and right-of-use assets in the statement of financial position upon adoption of ASU 2016-02.

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

Forward-Looking Statements

Certain statements in this report, including statements in the management's discussion and analysis section set forth below, may be considered "forward-looking statements" as that term is defined in the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by the words "expect," "estimate," "plan", "project," "anticipate," "should," "intend," "may," "will," "believe," "continue" or other words and terms of similar meaning in connectio any discussion of, among other things, future operating or financial performance, strategic initiatives and business strategies, regulatory or competitive environments, our intellectual property and product development. In particular, these forward-looking statements include, among others, statements about:

- our expectations regarding commercialization and sales of OTREXUP® (methotrexate) injection;
- our expectations regarding the ability of our partner Teva Pharmaceutical Industries, Ltd.'s ("Teva") to successfully commercialize Sumatriptan Injection USP;
- our expectations regarding product development and potential approval by the United States Food and Drug Administration ("FDA") of XYOSTED™ (testosterone enanthate) injection for testosterone replacement therapy;
- our expectations regarding continued product development with Teva, and potential FDA approval of the VIBEX® Epinephrine Pen ("epinephrine auto injector"), teriparatide disposable pen injector and exenatide disposable pen injector, and Teva's ability to successfully commercialize each of those products;
- our expectations regarding continued product development with our partner AMAG Pharmaceuticals, Inc. ("AMAG"), and potential FDA approval of an auto injector for Makena®;
- our expectations regarding trends in pharmaceutical drug delivery characteristics;
- our anticipated continued reliance on third-party contract manufacturers to manufacture our products;
- our anticipated continued reliance on third parties to provide certain services for our products including logistics, warehousing, distribution, invoicing, contract administration and chargeback processing;
- our sales and marketing plans;
- our product development and commercialization plans regarding our other products and product candidates;
- the timing and results of our clinical trials, research and development projects;
- our future cash flow and our ability to support our operations;