

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.

INDEX

	PAGE
PART I. <u>FINANCIAL INFORMATION</u>	3
Item 1. <u>Financial Statements</u>	3
<u>Consolidated Balance Sheets, as of June 30, 2017 (Unaudited) and December 31, 2016</u>	3
<u>Consolidated Statements of Operations (Unaudited) for the three and six months ended June 30, 2017 and 2016</u>	4
<u>Consolidated Statements of Comprehensive Loss (Unaudited) for the three and six months ended June 30, 2017 and 2016</u>	5
<u>Consolidated Statements of Cash Flows (Unaudited) for the six months ended June 30, 2017 and 2016</u>	6
<u>Notes to Consolidated Financial Statements (Unaudited)</u>	7
Item 2. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	14
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	24
Item 4. <u>Controls and Procedures</u>	24
PART II. <u>OTHER INFORMATION</u>	25
Item 1. <u>Legal Proceedings</u>	25
Item 1A. <u>Risk Factors</u>	25
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	25
Item 3. <u>Default Upon Senior Securities</u>	25
Item 4. <u>Mine Safety Disclosures</u>	25
Item 5. <u>Other Information</u>	25
Item 6. <u>Exhibits</u>	26

SIGNATURES

2

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	—	1,551,677
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.

3

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		For the Six Months Ended	
	Ended		June 30,	
	June 30,	2016	2017	2016
Net loss	2017	2016	2017	2016
	\$(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 withholding 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 Weighted Average Grant		Restricted Stock Units Weighted Average Grant	
	Number of Shares	Date Fair Value	Number of Shares	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		Six Months Ended	
	June 30,		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		Six Months Ended	
	June 30,		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 connection with 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;
- our estimates and expectations regarding the sufficiency of our cash resources, anticipated capital requirements and our need for and ability to obtain additional financing;
- the impact of new accounting pronouncements and our expectations and estimates with regard to current accounting practices; and
- our expectations regarding our financial and operating results for the year ending December 31, 2017.

Forward-looking statements are based on assumptions that we have made in light of our industry experience as well as our perceptions of historical trends, current conditions, expected future developments and other factors we believe are appropriate under the circumstances. As you read and consider this report, you should understand that these statements are not guarantees of performance results. Forward-looking statements involve known and unknown risks, uncertainties and assumptions, and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. While we believe that we have a reasonable basis for each forward-looking statement contained in this report, we caution you that these statements are based on a combination of facts and factors currently known by us and projections of the future about which we cannot be certain. Many factors may affect our ability to achieve our objectives, including:

- delays in product introduction and marketing or interruptions in supply;
- a decrease in business from our major customers and partners;
-

our inability to compete successfully against new and existing competitors or to leverage our research and development capabilities and our marketing capabilities;

- our inability to effectively market our products and services or obtain and maintain arrangements with our customers, partners and manufacturers;
- our inability to obtain adequate third-party payor coverage of our marketed products;
- our inability to effectively protect our intellectual property;
- costs associated with future litigation and the outcome of such litigation;
- our inability to attract and retain key personnel;
- changes or delays in the regulatory process;
- adverse economic and political conditions; and
- our ability to obtain additional financing, reduce expenses or generate funds when necessary.

In addition, you should refer to the “Risk Factors” sections of this report and of our Annual Report on Form 10-K for the year ended December 31, 2016 for a discussion of other factors that may cause our actual results to differ materially from those described by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements contained in this report will prove to be accurate and, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material.

We encourage readers of this report to understand forward-looking statements to be strategic objectives rather than absolute targets of future performance. Forward-looking statements speak only as of the date they are made. We do not intend to update publicly any forward-looking statements to reflect circumstances or events that occur after the date the forward-looking statements are made or to reflect the occurrence of unanticipated events except as required by law. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, if at all.

The following discussion and analysis, the purpose of which is to provide investors and others with information that we believe to be necessary for an understanding of our financial condition, changes in financial condition and results of operations, should be read in conjunction with the financial statements, notes thereto and other information contained in this report.

Overview

Company and Product Overview

Antares Pharma, Inc. (“Antares,” “we,” “our,” “us” or the “Company”) is an emerging, specialty pharmaceutical company that focuses on the development and commercialization of self-administered parenteral pharmaceutical products and technologies. Our strategy is to identify new or existing approved drug formulations and apply our drug delivery technology to enhance the drug compounds and delivery methods. We develop, manufacture and commercialize, for ourselves or with partners, novel therapeutic products using our advanced drug delivery systems that are designed to help improve safety and efficacy, reduce side effects, and enhance patient comfort and adherence. Our 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. We have a portfolio of proprietary and partnered products, including approved commercial products and several product candidates in advanced stages of development and under active FDA review. We have formed significant strategic alliances and partnership arrangements with industry leading pharmaceutical companies including Teva, AMAG, and Ferring Pharmaceuticals Inc. and Ferring B.V. (together “Ferring”).

We market and sell our proprietary product OTREXUP[®] (methotrexate) injection, which was launched in the U.S. in February 2014. OTREXUP[®] is the first FDA-approved subcutaneous methotrexate for once weekly self-administration with an easy-to-use, single dose, disposable auto injector, indicated for adults with severe active

rheumatoid arthritis, children with active polyarticular juvenile idiopathic arthritis and adults with severe recalcitrant psoriasis. To date, we have received FDA approval for dosage strengths of 7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg, 22.5 mg and 25 mg of OTREXUP®.

With our commercialization partner Teva, we launched Sumatriptan Injection USP, indicated in the U.S. for the acute treatment of migraine and cluster headache in adults, in June 2016. We received FDA approval of our 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®, in December 2015. Sumatriptan Injection USP represents the Company’s first ANDA approval of a complex generic and second product approved using the VIBEX® auto injector platform and is commercialized and distributed by Teva under the terms of a license, supply and distribution arrangement.

We also make reusable, needle-free injection devices that administer injectable drugs, which are currently marketed primarily through our partner Ferring, for use with human growth hormone, and have two gel-based products that are commercialized through our partners pursuant to licensing arrangements.

Overview of Clinical, Regulatory and Product Development Activities

We are 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. We conducted a multi-center, phase 3 clinical study (“QST-13-003”) evaluating the efficacy and safety of testosterone enanthate administered once-weekly by subcutaneous injection using the QuickShot® auto injector in adult males diagnosed with testosterone deficiency, and we previously announced positive top-line pharmacokinetic results that showed that the primary endpoint for this study was achieved. Based upon a written response we received from the FDA related to our clinical development program for XYOSTED™, we conducted an additional supplemental safety study QST-15-005. The study included a screening phase, a treatment titration phase and a treatment phase for evaluation of safety and tolerability assessments, including laboratory assessments, adverse events and injection site assessments. In September 2016, we announced the successful completion of the QST-15-005 study. The results of these two studies formed the clinical basis of our NDA submission for XYOSTED™ and are further discussed in the “Research and Development Programs” section below.

We are collaborating with Teva on a VIBEX® auto injector pen containing epinephrine used for the treatment of severe allergic reactions (anaphylaxis). Teva submitted an amendment to the VIBEX® epinephrine pen ANDA in December 2014 and received a Complete Response Letter (“CRL”) from the FDA in February 2016 in which, according to Teva, the FDA identified certain major deficiencies. Teva has advised us that they submitted a response to the CRL and are targeting a launch in early 2018.

Our other combination product development projects in collaboration with Teva include a multi-dose pen for a generic form of BYETTA® (exenatide injection) for the treatment of diabetes, and another multi-dose pen for a generic form of Forteo® (teriparatide [rDNA origin] injection) for the treatment of osteoporosis. Teva filed an ANDA for exenatide, which was accepted by the FDA in October 2014 and is currently under FDA review. In 2016, we announced that Teva had settled the patent litigation with AstraZeneca Pharmaceuticals, LP, AstraZeneca AB, and Amylin Pharmaceuticals, LLC (collectively “AstraZeneca”) relating to certain AstraZeneca U.S. patents and their drug, BYETTA® (exenatide). AstraZeneca and Teva entered into a settlement and license agreement pursuant to which AstraZeneca granted Teva a license to manufacture and commercialize the generic version of BYETTA® described in Teva’s ANDA. The settlement allows Teva to commercialize their exenatide product in the U.S. beginning October 15, 2017 or earlier under certain circumstances. Teva also filed an ANDA for a generic version of Forteo® (teriparatide [rDNA origin] injection), which was accepted by the FDA in February 2016 and is currently under review. In response to Teva’s paragraph IV certification contained in Teva’s ANDA for teriparatide, Eli Lilly & Co (“Lilly”) filed a lawsuit against Teva alleging infringement of six U.S. patents related to Forteo® (teriparatide [rDNA origin] injection) resulting in a 30-month stay in FDA approval of the ANDA. The stay will expire in August 2018 unless the litigation is resolved sooner. Teva also successfully concluded a decentralized procedure registration process in Europe. According to Teva, the Public Assessment Report for the decentralized procedure has been published and the product was filed in 17 countries, which addresses the majority of the market value in Europe.

In partnership with AMAG, we are currently developing a variation of our VIBEX® QuickShot® subcutaneous auto injector for use with AMAG’s Maken® (hydroxyprogesterone caproate injection) for the treatment of pre-term birth. Under a license, development and supply agreement, AMAG is responsible for the clinical development and preparation, submission and maintenance of all regulatory applications, the manufacture and supply of the drug, and the marketing, sale and distribution of the product. We are responsible for the design and development of the

auto-injection device, the manufacturing and supply of the device, and assembly and packaging of the final product. AMAG initiated a pharmacokinetic (“PK”) study in October 2016 and disclosed positive top line results of the study in February 2017. According to AMAG, the study successfully demonstrated comparable bioavailability between subcutaneous injection of Makena[®] compared to intra muscular injection. AMAG submitted its sNDA for the Makena[®] subcutaneous auto injector in April 2017, which was accepted by the FDA and given a PDUFA target action date of February 14, 2018.

Critical Accounting Policies

Our management's discussion and analysis of our results of operations and financial condition is based upon our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of our financial statements in accordance with GAAP requires us to make judgments and estimates that affect the reported amounts of assets, liabilities, revenues and expenses. We have identified certain of our significant accounting policies that we believe to be the most critical to the understanding our results of operations and financial condition because they require the most subjective and complex judgments. The following supplements our critical accounting policies, which are fully described under "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2016.

Revenue Recognition—OTREXUP

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

Prior to the first quarter of 2017, we could not reliably estimate expected returns of OTREXUP® at the time of shipment given our 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 that 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, we determined we had developed sufficient historical information to reasonably estimate future returns of OTREXUP® and began recognizing revenue upon delivery to the distributors, net of estimated returns. Accordingly, we recognized \$1,297,054 in revenue for product shipped to distributors in previous periods but not previously recognized as revenue at the time of shipment, net of the returns allowance established during the first quarter of 2017. We also recognized \$254,425 of related product costs in the first quarter of 2017. The net impact of these changes resulted in a decrease to net loss of \$1,042,629, or less than \$0.01 per share, for the six months ended June 30, 2017.

Results of Operations

We reported net losses of \$2,839,944 and \$6,061,463 for the three months ended June 30, 2017 and 2016, respectively, and \$7,575,861 and \$13,717,573 for the six months ended June 30, 2017 and 2016, respectively. Net loss per share was \$0.02 for the three months ended June 30, 2017 as compared to \$0.04 for the three months ended June 30, 2016, and \$0.05 and \$0.09 for the six months ended June 30, 2017 and 2016, respectively. 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. The following is an analysis and discussion of our operations for the three and six months ended June 30, 2017 as compared to the same periods in 2016.

Revenues

Three months ended		Six months ended June 30,	
June 30,		2017	2016
2017	2016	2017	2016

Edgar Filing: ANTARES PHARMA, INC. - Form 10-Q

OTREXUP®	\$3,923,042	\$3,810,291	\$8,487,163	\$7,120,065
Auto injector and pen injector devices	2,435,216	3,913,505	6,543,526	9,892,393
Needle-free injector devices and components	986,155	966,206	2,350,536	2,518,591
Total 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

Total revenue for the three months ended June 30, 2017 and 2016 was \$13,416,159 and \$12,228,390, respectively, representing an increase in total revenue of 10% on a comparative basis. Revenue for the six months ended June 30, 2017 was \$25,423,618 as compared to \$24,547,162 for the six months ended June 30, 2016, representing an increase of 4%. The following is a detailed discussion of the components of and changes in revenue.

OTREXUP®

For the three months ended June 30, 2017 and 2016, we recognized revenue of \$3,923,042 and \$3,810,291, respectively, from sales of OTREXUP®, which is presented net of estimated product returns and sales allowances. We believe the increase in revenue for the three months ended June 30, 2017 as compared to the three months ended June 30, 2016 was driven by an increase in shipments to distributors and an underlying growth in prescriptions dispensed. However, as discussed in our “Critical Accounting Policies” above, we began recognizing revenue upon delivery to distributors, net of estimated returns, in the first quarter of 2017. Prior to the first quarter of 2017, due to lack of sufficient sales and returns history, revenue was initially deferred upon shipment to distributors and recognized based on estimated prescriptions dispensed or expiration of customer right of return. This change in estimation and recognition method may affect the comparability of revenues on a period over period basis.

We recognized revenues of \$8,487,163 and \$7,120,065 from OTREXUP® sales for the six months ended June 30, 2017 and 2016, respectively. The increase in OTREXUP® revenue for the six months ended June 30, 2017 as compared with the same period in 2016 included the recognition of \$1,297,054 in previously deferred revenue. If we underestimate or overestimate product returns for a given period, adjustments to revenue may be necessary in future periods.

Auto injector and pen injector devices

Product sales of auto injector devices were \$2,435,216 and \$3,913,505 for the three months ended June 30, 2017 and 2016, respectively, and \$6,543,526 and \$9,892,393 for the six months ended June 30, 2017 and 2016, respectively. The decrease in revenue for the three and six months ended June 30, 2017 as compared to 2016 was primarily due to the reduction in sales of pre-launch quantities of auto injector devices for use with Teva’s generic epinephrine product. The net decrease in revenue for the six months ended June 30, 2017 compared to 2016 was partially offset by an increase in sales of Sumatriptan Injection USP, which was launched in June 2016 and discussed in more detail below.

Revenue from auto injector sales for the three months ended June 30, 2017 was principally attributable to sumatriptan product sold to Teva, including the profit sharing payment received during the quarter. Revenue for the three months ended June 30, 2016 included \$967,000 of pre-launch quantities of auto injector devices sold to Teva for use with their generic epinephrine product, and approximately \$2,947,000 in pre-launch quantities of sumatriptan product at cost. Under a license, supply and distribution agreement with Teva for the sumatriptan product, we produce the devices, assemble and supply the final combination product, and Teva is responsible for distribution. We are compensated at cost for shipments of product to Teva and are entitled to receive 50 percent of the net profits from commercial sales made by Teva, which is payable to us within 45 days after the end of each fiscal quarter in which commercial sales are made.

For the six months ended June 30, 2017, approximately \$5,889,000 or 90% of the auto injector revenue was attributable to sales of sumatriptan product and related profit sharing received under the distribution agreement with Teva. For the six months ended June 30, 2016, approximately \$2,947,000 or 30% of the auto injector revenue was attributable to pre-launch quantities of sumatriptan product sold to Teva at cost, and \$6,946,000 or 70% derived from sales of pre-launch quantities of auto injector devices sold to Teva for use with their generic epinephrine product. As previously discussed, Teva’s ANDA for the epinephrine auto injector is under review by the FDA and Teva is targeting a launch in early 2018.

Needle-free injector devices and components

Our revenue from reusable needle-free injector devices and disposable components was \$986,155 and \$966,206 for the three months ended June 30, 2017 and 2016, respectively, and \$2,350,536 and \$2,518,591 for the six months ended June 30, 2017 and 2016 respectively. These revenues were relatively consistent on a period over period basis and are generated primarily from sales to Ferring, which sells our needle-free injector for use with its hGH products in Europe, Asia and the U.S. We do not control our partners' sales volume or inventory levels of our injectors and components, which can cause fluctuations in our product sales in comparative periods.

Development revenue

Development revenue typically represents amounts earned under arrangements with partners for which we develop new products on their behalf. Frequently, we receive up-front and milestone payments from our partners that are initially deferred and recognized as revenue over a development period or upon completion of defined deliverables. Development revenue was \$4,787,672 and \$3,267,397 for the three months ended June 30, 2017 and 2016, respectively, and was \$6,409,549 and \$4,365,771 for the six months ended June 30, 2017 and 2016, respectively. The increase in development revenue recognized for the comparative three and six-month periods was primarily a result of increases in development activities with AMAG for the Makena[®] auto injector product and

with Teva for the exenatide and teriparatide pen injector products, offset by a reduction in revenue for development activities with Teva in connection with the epinephrine auto injector.

Licensing Revenue

Licensing revenue represents amounts received from partners for the right to use certain intellectual property. Generally, the up-front or milestone payments received were initially deferred and recognized in revenue over the license period. We recognized \$1,019,040 and \$38,721 for the three months ended June 30, 2017 and 2016, respectively and \$1,037,718 and \$89,422 for the six months ended June 30, 2017 and 2016, respectively. The significant increase in licensing revenue recognized in the three and six months ended June 30, 2017 is due to the recognition of \$1,000,000 in licensing fees previously received and initially deferred due to potential contractual refund rights of the customer under certain circumstances. During the second quarter of 2017, the License, Supply and Distribution Agreement with Teva for Sumatriptan Injection USP was amended such that the refund provisions relating to the licensing fee was removed. Accordingly, we recognized the deferred revenue in income, as the license had been delivered and there were no remaining obligations related to the license granted.

Royalties

Royalty revenue was \$265,034 and \$232,270 for the three months ended June 30, 2017 and 2016, respectively and \$595,126 and \$560,920 for the six months ended June 30, 2017 and 2016, respectively. We receive royalties from Ferring related to needle-free injector device sales and on sales of ZOMACTON™ in the U.S., and on sales of gel-based products commercialized through partners.

Cost of Revenue and Gross Profit

The following table summarizes our total revenue, cost of revenue and gross profit:

	Three months ended June 30,		Six months ended June 30,		
	2017	2016	2017	2016	
Total revenue	\$13,416,159	\$12,228,390	\$25,423,618	\$24,547,162	
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	
Gross profit percentage	58	% 40	% 53	% 43	%

Our gross profit was \$7,799,770 and \$13,587,463 for the three and six months ended June 30, 2017, respectively, as compared to \$4,910,292 and \$10,453,323 for the three and six months ended June 30, 2016, respectively. The increase in our gross profit for the three months ended June 30, 2017 was primarily attributable to the increase in profit recognized on development activities completed during the period and the recognition of \$1,000,000 in licensing revenue previously deferred, for which there was no associated costs. The increase in gross profit for the six months ended June 30, 2017 compared to the same period in 2016 was also attributable to the recognition of previously deferred revenue related to OTREXUP® sales and other changes in our product revenue and cost of sales, which is summarized in the following table and discussed below.

Edgar Filing: ANTARES PHARMA, INC. - Form 10-Q

	Three months ended		Six months ended June 30,	
	June 30, 2017	2016	2017	2016
Product sales	\$7,344,413	\$8,690,002	\$17,381,225	\$19,531,049
Cost of product sales	3,633,218	5,216,527	9,081,509	11,464,083
Product gross profit	\$3,711,195	\$3,473,475	\$8,299,716	\$8,066,966
Product gross margin percentage	51	% 40	% 48	% 41

Product gross profit increased in the three months ended June 30, 2017 as compared to the three months ended June 30, 2016, primarily due to sales of Sumatriptan Injection USP, which is initially sold at cost to Teva, and profit recognized from the margin sharing arrangement in trailing periods. The increase in product gross profit for the six months ended June 30, 2017 compared to the six months ended June 30, 2016 included the \$1,042,629 net impact of recognizing previously deferred revenue and related product costs for OTREXUP® as described in “Critical Accounting Policies” above, and sales of Sumatriptan Injection USP, which was launched in June 2016. These increases were offset by the reduction in epinephrine auto injector device sales and the associated cost of sales. The cost of product sales includes product acquisition costs from third-party manufacturers and internal manufacturing overhead expenses.

Other variations in revenue, cost of revenue and gross profit are attributable to our development activities, which fluctuate depending on the mix of development projects in progress and stages of completion in each period. The cost of development revenue consists primarily of direct external costs, some of which may have been previously incurred and deferred. The cost of development revenue in each period was primarily related to revenue recognized under the Teva auto injector and pen injector programs and development of the Makena® auto injector with AMAG.

Research and Development

Research and development expenses consist of external costs for clinical studies and analysis activities, design work and prototype development, FDA fees, personnel costs and other general operating expenses associated with our research and development activities. Research and development expenses were \$3,159,363 and \$3,948,020 for the three months ended June 30, 2017 and 2016, respectively, and \$6,245,644 and \$9,596,049 for the six months ended June 30, 2017 and 2016, respectively. The decrease in research and development costs on a comparative basis is primarily due to a decrease in external clinical and development costs related to XYOSTED™ for testosterone replacement therapy. We completed clinical trials and submitted our NDA for XYOSTED™ to the FDA in the fourth quarter of 2016.

Selling, General and Administrative

Selling, general and administrative expenses were \$7,360,010 and \$7,014,520 for three months ended June 30, 2017 and 2016, respectively and \$14,827,265 and \$14,617,698 for the six months ended June 30, 2017 and 2016, respectively. The overall increase was primarily attributable to an increase in pre-launch sales and marketing expenses associated with XYOSTED™.

Liquidity and Capital Resources

At June 30, 2017, we had cash and cash equivalents of \$33,418,393 and short-term investments of \$9,960,479. Our principal liquidity needs are to fund our research and development activities and for the payment of other operating expenses. We have not historically generated, and do not currently expect to generate, enough revenue or operating cash flow to support or grow our operations and we continue to operate primarily by raising capital. Our primary sources of liquidity are proceeds from equity offerings and debt issuance. We believe that the combination of our current cash and cash equivalents, short-term investments, projected product sales, development revenue milestones and royalties will provide us with sufficient funds to meet our obligations and support operations through at least the next twelve months from the date of this report.

Long-Term Debt Financing

On June 6, 2017, we entered into a loan and security agreement 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, we may, but are 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 option to request additional advances must be exercised prior to September 30, 2018. 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 certain corporate milestones are achieved. The Loan Agreement also requires us 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.

Net Cash Flows from Operating Activities

Operating cash inflows are generated primarily from product sales, license and development fees and royalties. Operating cash outflows consist principally of expenditures for manufacturing costs, personnel costs, general and administrative expenses, research and development projects, and sales and marketing activities. Fluctuations in cash used in operating activities are primarily a result of the timing of cash receipts and disbursements. Net cash used in operating activities was \$10,094,441 for the six months ended June 30, 2017 and \$8,683,126 for the six months ended June 30, 2016. For the six months ended June 30, 2017, the net cash used in operating activities was primarily driven by our net loss, adjusted for non-cash operating costs such as depreciation, amortization and share-based compensation, plus changes in accounts payable, offset by additional inventory purchases and the release of OTREXUP[®] deferred revenues in connection with the change in revenue recognition method.

Net Cash Flows from Investing Activities

Net cash used in investing activities for the six months ended June 30, 2017 was \$10,550,187 as compared to net cash provided by investing activities of \$3,405,807 for the six months ended June 30, 2016. The net cash outflow for the six months ended June 30,

2017, was attributable to purchases of investment securities of \$9,963,978 and payments for capital expenditures and patent acquisition costs totaling \$586,209, while the net cash inflow for the six months ended June 30, 2016 was attributable to maturities of investment securities of \$6,000,000, offset by payments for capital expenditures and patent acquisition costs totaling \$2,594,193.

Net Cash Flows from Financing Activities

Cash flow provided by financing activities was \$26,348,773 for the six months ended June 30, 2017, attributable to the receipt of \$25,000,000 proceeds from debt issuance and \$1,590,204 cash proceeds received from the exercise of stock options offset by payments of debt issuance costs and tax withholding payments in connection with settlement of share-based awards. Cash used in financing activities was \$64,096 for the six months ended June 30, 2016, related to cash remitted to taxing authorities in connection with net-share settled awards for which we withheld shares equivalent to the value of the employees' minimum statutory obligation for the applicable income and other employment taxes.

Contractual Obligations

The following table presents our contractual obligations and the related payments, including interest, due by period as of June 30, 2017:

	Payments Due by Period				
	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Long-Term Debt Obligations	\$34,000,014	\$2,127,778	\$11,012,670	\$18,940,522	\$1,919,044
Operating Lease Obligations	2,034,993	626,688	993,745	414,560	—
Total	\$36,035,007	\$2,754,466	\$12,006,415	\$19,355,082	\$1,919,044

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, including any arrangements with any structured finance, special purpose or variable interest entities.

Research and Development Programs

We conduct clinical, regulatory, formulation development, parenteral device development and commercial development activities for internal and partnered products. The following is a discussion of our significant research and development programs.

XYOSTED™ (Formerly referred to as VIBEX® QuickShot® Testosterone or “QST”). We are developing XYOSTED™ for self-administered weekly injections of testosterone enanthate for clinically diagnosed testosterone deficient men requiring testosterone replacement therapy.

On December 5, 2012, we conducted a pre-IND (Investigational New Drug application) meeting with the FDA as part of preparing to initiate clinical development of XYOSTED™, establishing an agreed upon clinical path forward. In September 2013, we announced that the first patients were dosed in a clinical study evaluating the PK profile of testosterone enanthate administered weekly by subcutaneous injection at doses of 50 mg and 100 mg via the

XYOSTED™ auto injector device in testosterone deficient adult males. The study enrolled 39 patients at nine investigative sites in the U.S. We announced our top line results of this study in a press release on February 20, 2014. We believe that the results are positive in that XYOSTED™ treatment resulted in most patients achieving average levels of testosterone within the normal range from the first dose onward. XYOSTED™ was also safe and well tolerated by all dosed patients.

On November 3, 2014, we announced that the last patient had been enrolled in a double-blind, multiple-dose, phase III study (QST-13-003) to evaluate the efficacy and safety of XYOSTED™ administered subcutaneously once each week to testosterone-deficient adult males. Patients enrolled in this study had a documented diagnosis of hypogonadism or testosterone deficiency defined as having testosterone levels below 300 ng/dL. The study includes a screening phase, a treatment titration and efficacy phase and an extended treatment phase. One hundred fifty patients were enrolled in this study. Patients meeting all eligibility criteria were assigned to receive a starting dose of XYOSTED™ once weekly for six weeks. Adjustments to dose could be made at week seven based upon the week six pre-dose blood level. The efficacy of XYOSTED™ and dose adjustment to regulate testosterone levels were evaluated after 12 weeks of treatment.

On February 25, 2015, we announced positive top-line pharmacokinetic results that showed that the primary endpoint was achieved in QST-13-003. The protocol for the study required that at the week 12 endpoint: (i) at least 75% of all patients' C_{avg} are within the normal range of 300 to 1100 ng/dL, with a lower limit of a 95% 2-sided confidence interval of greater than or equal to 65%, (ii) at least 85% of patients' C_{max} are less than 1500 ng/dL and (iii) no more than 5% of patients had a C_{max} greater than 1800 ng/dL. The primary endpoint of the population that received one or more doses of XYOSTED™ was met by 139 out of 150 patients, equating to 92.7% with a 95% confidence interval of 87.3% to 96.3%. Among the 137 patients that completed all 12 weeks of dosing and PK sampling, 98.5% were within the pre-defined range. The top-line results of the PK study are summarized in the table below.

Population/Analysis	C_{avg} Lower	C_{avg} % in range	C_{max} <1500	C_{max} >1800
	limit of the 95% 2-sided			
	C. I.	n (%)	n (%)	n (%)
Primary analysis* N=150	87.3	% 139 (92.7)	% 137 (91.3)	%** 0
Completers N=137	94.8	% 135 (98.5)	% 137 (100)	% 0
Protocol-Required Outcomes	≥65	% 75	% ≥85	% ≤5

* All patients with 1 or more doses, C_{avg} 0-168 hours post week 12 injection or last measured concentration carried forward

** Patients without a C_{max} determination at week 12 are assigned above 1500 ng/dL

Overall, the regimen demonstrated a mean (\pm standard deviation) steady state concentration of testosterone of 553.3 \pm 127.3 ng/dL at 12 weeks. Participants in the study remained on XYOSTED™ and were followed for an additional 40 weeks for the collection of safety data.

After we initiated study QST-13-003, but before we announced positive top-line pharmacokinetic results in February 2015, we received written recommendations from the FDA related to our clinical development program for XYOSTED™. The recommendations received were in response to various clinical, chemistry, manufacturing and controls and user study submissions that we made through November 2014. We believe that we had already factored many of the recommendations cited in the advice letter into the protocol of the ongoing QST-13-003 study and into the protocols for planned human use studies as a result of guidance provided by the FDA at the May 2014 Type C meeting. Based on a single reported occurrence of hives in our phase 2 study, the FDA recommended that we create a larger safety database, including approximately 350 subjects exposed to XYOSTED™ with approximately 200 subjects exposed for six months and approximately 100 subjects exposed for a year. We assessed the FDA's comments in the advice letter and their impact on the timing of the filing of a NDA for XYOSTED™ with the FDA. Based on the number of subjects in previous studies and in the current QST-13-003 study, we concluded that we would need additional subjects exposed to XYOSTED™ for six months. The timing and design of the study to obtain the additional subjects and data required was determined based on further discussion with the FDA. We submitted our response to the FDA's written recommendations in early March 2015.

In October 2015, we announced that the last patient in study QST-13-003 received their week 52 treatment, which marked the end of the treatment phase of this study. In March 2016, we announced that the pharmacokinetic results of QST-13-003 were final and reported the results from the 52-week safety study. The safety population, defined as patients who received at least one dose of study drug, was comprised of 150 patients. The most common adverse

reactions (incidence $\geq 5\%$) in this phase 3 study were increased hematocrit, hypertension, increased prostate-specific antigen, upper respiratory tract infection, sinusitis, injection site bruising and headache. Serious adverse events (SAE's) reported included one case each of worsening depression, vertigo and suicide. None of the SAE's were considered to be related to the study drug by the investigators, however the Company determined that the case of suicide could not be ruled out as potentially being related to study drug. There have been no reported adverse events consistent with urticaria (hives), pulmonary oil micro embolism ("POME"), anaphylaxis or major adverse cardiovascular events in this study.

In May 2015, we received an additional written update from the FDA related to our clinical development program for XYOSTED™. Based on that update received from the FDA, we concluded there was an agreed upon path forward for the completion of an additional study to support the filing of a NDA for XYOSTED™. In June 2015, we finalized and submitted the protocol for the study, and in August 2015, we enrolled the first patients in the study, which is known as QST-15-005. The study was a dose-blind, multiple-dose, concentration controlled 26-week supplemental safety and pharmacokinetic study of XYOSTED™, which included a screening phase, a treatment titration phase, and a treatment phase for evaluation of safety and tolerability assessments including laboratory assessments, adverse events and injection site assessment. Patients meeting all eligibility criteria were assigned to receive 75 mg of XYOSTED™ once weekly for six weeks. According to the protocol, adjustments to dose could be made at week seven based upon the week six C_{trough} value. XYOSTED™ was provided to clinical sites at dosage strengths of 100 mg, 75 mg and 50 mg to be utilized in dose titration.

In early November 2015, the Company announced that enrollment was complete in study QST-15-005. The safety population, defined as patients who received at least one dose of the study drug, consisted of 133 patients dosed with XYOSTED™. In June 2016, we announced that the last patient had completed treatment under the 26-week safety and pharmacokinetic phase 3 study QST-15-005, and in September 2016 we announced the results of the study. The most common adverse reactions (incidence $\geq 5\%$) in the QST-15-005 study were increased hematocrit, upper respiratory tract infection and injection site ecchymosis. There were four patients with treatment emergent SAE's, which included one patient with transient visual impairment determined not to be drug related, one patient with appendicitis that was not drug related and one patient with deep vein thrombosis ("DVT"). The investigator attributed DVT as possibly drug related, which is consistent with known testosterone class SAE's. The fourth patient had multiple hospitalizations related to septic arthritis and coronary artery disease, with a complicated clinical course post-angioplasty. These multiple reported events from the fourth patient were deemed not to be drug related. There were no reported adverse events consistent with urticaria, POME or anaphylaxis. The safety data collected also included an assessment of pain. Of the 965 injections assessed, pain was reported one time. In that instance, the pain reported was classified as mild.

Based upon the completion of our clinical and development work and the results of the studies detailed above, we submitted a 505 (b) (2) New Drug Application for XYOSTED™ to the FDA in December 2016. The NDA submission was accepted for standard review by the FDA and assigned a PDUFA target date for completion of its review by October 20, 2017.

Device Development Projects. We, along with our pharmaceutical partners, are engaged in research and development activities related to our VIBEX® disposable pressure assisted auto injectors and our disposable pen injectors. We have signed license agreements with Teva for our VIBEX® system for a product containing epinephrine and for our pen injector devices for use with generic versions of BYETTA® (exenatide) and Forteo® (teriparatide). We also have a license, development and supply agreement with AMAG for our auto injector device for use with its drug Makena®. The development programs consist of determination of the device design, development of prototype tooling, production of prototype devices for testing and clinical studies, and development of commercial tooling and assembly. We expect development related to these products to continue, however, the development timelines are generally controlled by our partners and the extent of near-term and future development will be dependent on decisions made by our partners. The following is a summary of the development stages for each of the products in development with Teva and AMAG.

Makena® (hydroxyprogesterone caproate injection) Auto Injector

We are in the process of developing a variation of our VIBEX® QuickShot® auto injector for use with the progestin hormone drug Makena® under a license, development and supply agreement with AMAG. Under this arrangement, AMAG is responsible for the clinical development and preparation, and submission and maintenance of all regulatory applications. We are responsible for the design and development of the auto-injection device.

AMAG initiated a PK study for the Makena® auto injector in October 2016 and announced positive top-line results of the study in February 2017. According to AMAG, the study successfully demonstrated comparable bioavailability between subcutaneous injection of Makena® compared to intra muscular injection. AMAG submitted its sNDA for the Makena® subcutaneous auto injector in April 2017, which was accepted by the FDA and given a PDUFA target action date of February 14, 2018.

VIBEX® with epinephrine

We, in collaboration with Teva, have developed a VIBEX® auto injector device for a product containing epinephrine. Teva is responsible for development work on the drug epinephrine, and we are responsible for development of the

device. Teva filed an ANDA for the VIBEX[®] epinephrine pen as a generic substitute of Mylan's branded product, EpiPen[®], which was accepted by the FDA, and amended in December 2014. We have scaled up the commercial tooling and molds for this product and delivered pre-launch quantities of the product in anticipation of a potential approval and launch. However, Teva received a CRL from the FDA in February 2016 in which, according to Teva, the FDA identified certain major deficiencies. Teva has advised us that they submitted a response to the CRL and are targeting a launch in early 2018.

Exenatide disposable pen injector

We have designed and produced a pen injector product for use with exenatide for Teva. Teva filed an ANDA for a generic version of BYETTA[®], which was accepted by the FDA in October 2014 and is currently under review. Teva settled patent litigation with AstraZeneca relating to certain AstraZeneca U.S. patents and their drug, BYETTA[®] (exenatide). AstraZeneca and Teva entered into a settlement and license agreement pursuant to which AstraZeneca granted Teva a license to manufacture and commercialize the generic version of BYETTA[®] described in Teva's ANDA. The settlement allows Teva to commercialize their exenatide product in the U.S., assuming FDA approval, beginning October 15, 2017 or earlier under certain circumstances.

Teriparatide disposable pen injector

We have designed and produced a multi-dose disposable pen injector for use with teriparatide for Teva and have delivered devices for a drug stability program to support a regulatory filing. Teva is developing this product for use in both Europe and the U.S. with the European clinical/regulatory team leading the development.

Teva filed an ANDA for a generic version of Forteo® (teriparatide [rDNA origin] injection), which was accepted by the FDA and is currently under review. In response to Teva's paragraph IV certification contained in Teva's ANDA for teriparatide, Lilly filed a lawsuit against Teva alleging infringement of six U.S. patents related to Forteo® (teriparatide [rDNA origin] injection) resulting in a 30-month stay in FDA approval of the ANDA. The stay will expire in August 2018 unless the litigation is resolved sooner. Teva also successfully concluded a decentralized procedure registration process in Europe. According to Teva, the Public Assessment Report for the decentralized procedure has been published and the product was filed in 17 countries, which addresses the majority of the market value in Europe.

Other Research and Development Costs. In addition to our development of XYOSTED™ and our device development projects with Teva and AMAG, we incur direct costs associated with other internal research and development projects and indirect costs that include personnel costs, administrative and other operating costs related to managing our research and development activities.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to foreign exchange rate fluctuations of the Swiss Franc to the U.S. dollar as the financial position and operating results of our subsidiaries in Switzerland are translated into U.S. dollars for consolidation. Our exposure to foreign exchange rate fluctuations also arises from transferring funds to our Swiss subsidiaries in Swiss Francs. In addition, we have exposure to exchange rate fluctuations between the Euro and the U.S. dollar in connection with a licensing agreement with Ferring, under which certain products sold to Ferring and royalties are denominated in Euros. Most of our product sales, including a portion of our product sales to Ferring, and our development and licensing fees and royalties are denominated in U.S. dollars, thereby significantly mitigating the risk of exchange rate fluctuations on trade receivables. We do not currently use derivative financial instruments to hedge against exchange rate risk. The effect of foreign exchange rate fluctuations on our financial results for the periods ended June 30, 2017 was not material.

We may be exposed to interest rate risk and interest rate fluctuations as a result of our long-term debt financing we obtained on June 6, 2017. Our Term Loan, with a current outstanding principal of \$25,000,000, accrues interest at a calculated prime-based variable rate with a maximum interest rate of 9.50%. The calculated prime-based variable rate was 8.75% at June 30, 2017. An increase to the maximum interest rate of 9.50% would result in additional incremental annual interest expense of \$187,500.

Item 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

The Company's management, under the supervision and with the participation of the Company's Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this report. The evaluation was performed to determine whether the Company's disclosure controls and procedures have been designed and are functioning effectively to provide reasonable assurance that the information required to be disclosed by the Company in reports filed under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and is accumulated and communicated to management, including the Company's principal executive and principal financial officers, or persons performing

similar functions, as appropriate to allow timely decisions regarding required disclosure. Based on such evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures as of the end of the period covered by this report were effective.

Internal Control over Financial Reporting

There have not been any changes in the Company's internal control over financial reporting during the fiscal quarter to which this report relates that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that

any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART II - OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

None.

Item 1A. RISK FACTORS

In addition to the other information contained in this report, you should carefully consider the risk factors discussed in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2016, which could materially affect our business, financial condition or future results. There have been no material changes to these risk factors other than the supplemental information and risk factors discussed below. The risks described in our Annual Report on Form 10-K are not the only risks facing us. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

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

None.

Item 3. DEFAULT UPON SENIOR SECURITIES

None.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Item 5. OTHER INFORMATION

None.

Item 6. EXHIBITS

(a) Exhibit Index

Exhibit No.	Description
10.1	Loan and Security Agreement dated June 6, 2017, by and among Antares Pharma, Inc., Hercules Capital, Inc., and the several banks and other financial institutions or entities from time to time party to the Loan Agreement (filed as Exhibit 10.1 to Form 8-K on June 7, 2017 and incorporated herein by reference.)
31.1#	<u>Certificate of the Chief Executive Officer of Antares Pharma, Inc. required by Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
31.2#	<u>Certificate of the Chief Financial Officer of Antares Pharma, Inc. required by Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
32.1##	<u>Certificate of the Chief Executive Officer of Antares Pharma, Inc. required by Rule 13a-14(b) under the Securities Exchange Act of 1934, as amended, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
32.2##	<u>Certificate of the Chief Financial Officer of Antares Pharma, Inc. required by Rule 13a-14(b) under the Securities Exchange Act of 1934, as amended, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
101.INS#	XBRL Instance Document
101.SCH#	XBRL Taxonomy Extension Schema Document
101.CAL#	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB#	XBRL Taxonomy Extension Label Linkbase Document
101.PRE#	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF#	XBRL Taxonomy Extension Definition Document

Filed herewith.

##Furnished herewith.

SIGNATURES

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

ANTARES PHARMA, INC.

August 8, 2017 /s/ Robert F. Apple
Robert F. Apple
President and Chief Executive Officer
(Principal Executive Officer)

August 8, 2017 /s/ Fred M. Powell
Fred M. Powell
Senior Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)