ANTARES PHARMA, INC.
Form 10-Q
May 09, 2016

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 March 31, 2016

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 x No o

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 x No o

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

Large accelerated filer ¨	Accelerated filer x
Non–accelerated filer o (do not check if a smaller reporting company)	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

The number of shares outstanding of the registrant's Common Stock, $.01 par value, as of May 5, 2016 was 154,927,660.

ANTARES PHARMA, INC.

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PART I – FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS
ANTARES PHARMA, INC.

CONSOLIDATED BALANCE SHEETS

	March 31, 2016 (Unaudited)	December 31, 2015
Assets		
Current Assets:		
Cash	$30,102,144	$32,898,676
Short-term investments	12,009,000	15,012,225
Accounts receivable	7,976,760	7,952,478
Inventories	5,270,049	5,724,397
Deferred costs	2,049,330	1,199,217
Prepaid expenses and other current assets	3,178,256	3,274,254
Total current assets	60,585,539	66,061,247
Equipment, molds, furniture and fixtures, net	17,142,571	14,793,084
Patent rights, net	2,331,347	2,434,542
Goodwill	1,095,355	1,095,355
Other assets	153,826	177,943
Total Assets	$81,308,638	$84,562,171
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$6,960,444	$5,187,703
Accrued expenses and other liabilities	8,530,420	6,488,032
Deferred revenue	5,254,028	5,143,825
Total current liabilities	20,744,892	16,819,560
Deferred revenue – long term	680,600	700,000
Total liabilities	21,425,492	17,519,560
Stockholders' Equity:		
Preferred Stock: $0.01 par, authorized 3,000,000 shares, none outstanding	—	—
Common Stock: $0.01 par; authorized 200,000,000 shares; 154,927,660 and 154,848,512 issued and outstanding at March 31, 2016 and December 31, 2015, respectively	1,549,277	1,548,485
Additional paid-in capital	295,792,964	295,292,414
Accumulated deficit	(236,762,612)	(229,106,502)
Accumulated other comprehensive loss	(696,483)	(691,786)
	59,883,146	67,042,611
Total Liabilities and Stockholders' Equity	$81,308,638	$84,562,171

See accompanying notes to consolidated financial statements.

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ANTARES PHARMA, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

	For the Three Months Ended March 31,	
	2016	2015
Revenue:		
Product sales	$10,841,047	$4,623,130
Development revenue	1,098,374	2,388,403
Licensing revenue	50,701	883,009
Royalties	328,650	453,495
Total revenue	12,318,772	8,348,037
Cost of revenue:		
Cost of product sales	6,247,556	1,957,573
Cost of development revenue	528,185	1,717,156
Total cost of revenue	6,775,741	3,674,729
Gross profit	5,543,031	4,673,308
Operating expenses:		
Research and development	5,648,029	4,377,981
Selling, general and administrative	7,603,178	7,037,290
Total operating expenses	13,251,207	11,415,271
Operating loss	(7,708,176)	(6,741,963)
Other income (expense)	52,066	(45,711)
Net loss	(7,656,110)	(6,787,674)
Basic and diluted net loss per common share	$(0.05)	$(0.05)
Basic and diluted weighted average common shares outstanding	154,858,079	131,744,741

See accompanying notes to consolidated financial statements.

ANTARES PHARMA, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(UNAUDITED)

	For the Three Months Ended March 31,	
	2016	2015
Net loss	$(7,656,110)	$(6,787,674)
Foreign currency translation adjustment	(4,697)	12,064
Comprehensive loss	$(7,660,807)	$(6,775,610)

See accompanying notes to consolidated financial statements.

ANTARES PHARMA, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	Three Months Ended March 31,	
	2016	2015
Cash flows from operating activities:		
Net loss	$(7,656,110)	$(6,787,674)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	535,819	733,695
Depreciation and amortization	413,545	378,555
Amortization of premiums and discounts	3,225	1,414
Changes in operating assets and liabilities:		
Accounts receivable	(37,737)	(694,369)
Inventories	454,348	(37,074)
Prepaid expenses and other assets	120,544	(684,112)
Deferred costs	(850,113)	205,257
Accounts payable	1,714,501	(392,895)
Accrued expenses and other current liabilities	1,249,595	(1,415,479)
Deferred revenue	88,577	(1,965,551)
Net cash used in operating activities	(3,963,806)	(10,658,233)
Cash flows from investing activities:		
Purchases of equipment, molds, furniture and fixtures	(1,766,979)	(1,889,615)
Additions to patent rights	(32,517)	(927,631)
Proceeds from maturities of investment securities	3,000,000	3,000,000
Net cash provided by investing activities	1,200,504	182,754
Cash flows from financing activities:		
Taxes paid related to net share settlement of equity awards	(34,476)	(11,277)
Net cash used in financing activities	(34,476)	(11,277)
Effect of exchange rate changes on cash	1,246	891
Net decrease in cash	(2,796,532)	(10,485,865)
Cash:		
Beginning of period	32,898,676	34,028,889
End of period	$30,102,144	$23,543,024
Supplemental disclosure of non-cash investing activities:		
Purchases of equipment, molds, furniture and fixtures recorded in accounts payable and accrued expenses	$1,505,273	$1,754,053
Additions to patent rights recorded in accounts payable and accrued expenses	$6,501	$32,629

See accompanying notes to consolidated financial statements.

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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 focusing on the development and commercialization of self-administered parenteral pharmaceutical products and technologies. The Company has multiple internal product development programs as well as numerous partnership arrangements with several industry leading pharmaceutical companies. The Company has formed strategic alliances with Teva Pharmaceutical Industries, Ltd. (“Teva”), Ferring Pharmaceuticals Inc. and Ferring B.V. (together “Ferring”), JCR Pharmaceuticals Co., Ltd. (“JCR”) and AMAG Pharmaceuticals, Inc. (“AMAG”). Through these relationships, the Company develops and applies its drug delivery systems in collaborations with the pharmaceutical partners to enhance the partners' drug compounds and delivery methods.

The Company develops and manufactures, for itself and with its partners, novel, pressure-assisted injector devices, with and without needles, which allow patients to self-inject drugs. It makes a reusable, needle-free spring action injection device which is marketed through its partners for use with human growth hormone (hGH). The Company has also developed variations of the needle-free injector by adding a small shielded needle to a pre-filled, single-use disposable injector, called the VIBEX® pressure assisted auto injection system. This system is an alternative to the needle-free system for use with injectable drugs in unit dose containers and is suitable for branded and generic injectables. Additionally, the Company developed a disposable multi-dose pen injector for use with standard cartridges, and has a portfolio of gel-based products which are commercialized through various partners.

In February 2014, the Company launched its product OTREXUP™ (methotrexate) injection, which is the first subcutaneous methotrexate for once weekly self-administration with an easy-to-use, single dose, disposable auto injector approved by the U.S. Food and Drug Administration (“FDA”). OTREXUP™ is indicated for adults with severe active rheumatoid arthritis, children with active polyarticular juvenile idiopathic arthritis and adults with severe recalcitrant psoriasis. 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 Sumatriptan Injection USP in adults for the acute treatment of migraine and cluster headache. Sumatriptan Injection USP is the Company’s first ANDA approval of a complex generic and second product approved using the VIBEX® auto injector platform.

Antares also has a pipeline of proprietary and partnered products at various stages of development. The Company is currently conducting clinical studies of VIBEX® QuickShot® Testosterone (“QS T”), for testosterone replacement therapy, and has initiated manufacturing development for a combination product for an undisclosed central nervous system indication.

2. Basis of Presentation and Significant Accounting Policies

The accompanying unaudited consolidated financial statements have been prepared in accordance with generally accepted accounting principles 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, 2015. Operating results for the three months ended March 31, 2016 are not necessarily indicative of the results that may be expected for the year ending December 31, 2016.

Investments

All investments are U.S. Treasury bills or U.S. Treasury notes that are classified as held-to-maturity because of the Company's positive intent and ability to hold the securities to maturity. The securities are carried at their amortized cost and the fair value of all securities is determined by quoted market prices. At March 31, 2016 and December 31, 2015, the Company's investments had a carrying value of $12,009,000 and $15,012,225, respectively. The fair value of the Company's investments approximated their carrying value as of March 31, 2016 and December 31, 2015.

Inventories

Inventories are stated at the lower of cost or market. 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 $800,000 at March 31, 2016 and December 31, 2015. Inventories consist of the following:

	March 31, 2016	December 31, 2015
Inventories:		
Raw material	$220,874	$ 305,149
Work in process	1,311,837	1,539,319
Finished goods	3,737,338	3,879,929
	$5,270,049	$ 5,724,397

OTREXUP™ Revenue Recognition

In February 2014, the Company began detailing OTREXUP™ to health care professionals in the U.S. and began shipping to wholesale pharmaceutical distributors, subject to rights of return within a period beginning six months prior to, and ending 12 months following, product expiration. Given the limited sales history of OTREXUP™, the Company currently cannot reliably estimate expected returns of the product at the time of shipment. Accordingly, recognition of revenue is deferred on product shipments of OTREXUP™ until the right of return no longer exists, which occurs at the earlier of the time OTREXUP™ units are dispensed through patient prescriptions or expiration of the right of return. Units dispensed are generally not subject to return, except in the rare cases where the product malfunctions or the product is damaged in transit. Patient prescriptions dispensed are estimated using third-party market prescription data. These third-party sources poll pharmacies, hospitals, mail order and other retail outlets for OTREXUP™ prescriptions and project this sample on a national level. The Company uses this third party prescription data, among other information, as a basis for revenue recognition in each reporting period. If patient prescriptions dispensed for a given period are underestimated or overestimated, adjustments to revenue may be necessary in future periods.

The Company will continue to recognize revenue upon the earlier to occur of prescription units dispensed or expiration of the right of return until it can reliably estimate product returns, at which time the Company will record a one-time increase in net revenue related to the recognition of revenue previously deferred. In addition, the costs of manufacturing OTREXUP™ associated with the deferred revenue are recorded as deferred costs, which are included in inventory, until such time as the related deferred revenue is recognized.

The Company recognized $3,309,774 in OTREXUP™ product revenue for the three months ended March 31, 2016 as compared to $3,004,309 for the three months ended March 31, 2015, which is presented net of product sales allowances for estimated wholesaler discounts, prompt pay discounts, chargebacks, rebates and patient discount programs. The Company had deferred revenue balances of $834,234 and $1,064,874 at March 31, 2016 and December 31, 2015, respectively, for OTREXUP™ product shipments, which is net of product sales allowances, discussed below.

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 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. 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 Plan is 21,000,000 and the maximum number of shares of stock that may be granted to any one participant during a calendar year is 1,000,000 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. As of March 31, 2016 the Plan had approximately 1,500,000 shares available for grant.

Stock Options

The following is a summary of stock option activity under the Plan as of and for the three months ended March 31, 2016:

	Number of Shares	Weighted Average Exercise Price ($)	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value ($)
Outstanding at December 31, 2015	9,480,497	2.19		
Granted	402,000	0.92		
Exercised	—	—		
Cancelled/Forfeited	(792,998)	1.80		
Outstanding at March 31, 2016	9,089,499	2.17	6.9	234,627

Exercisable at March 31, 2016	6,864,944	2.19	6.2	229,622

The per share weighted average fair values of all options granted during the three months ended March 31, 2016 and 2015 were estimated as $0.44 and $1.35, 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.

	March 31,	
	2016	2015
Risk-free interest rate	1.3 %	1.5 %
Annualized volatility	50.2%	54.8%
Weighted average expected life, in years	6.00	6.00
Expected dividend yield	0.0 %	0.0 %

There were no stock option exercises during the three months ended March 31, 2016 and 2015, respectively.

The Company recognized $562,200 and $641,000 in compensation expense related to stock options for the three months ended March 31, 2016 and 2015, respectively. As of March 31, 2016, there was approximately $2,000,000 of total unrecognized compensation cost related to nonvested outstanding stock options that is expected to be recognized over a weighted average period of approximately 2.01 years.

Long Term Incentive Program (LTIP)

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 over a performance period, which is typically three to five years.

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

	Performance Stock Units		Restricted Stock Units	
	Number of Shares	Weighted Average Grant Date Fair Value ($)	Number of Shares	Weighted Average Grant Date Fair Value ($)
Outstanding at December 31, 2015	956,178	2.40	714,828	2.32
Granted	—		—	
Vested/settled	—		(112,298)	2.41
Forfeited/expired	—		(194,142)	2.31
Outstanding at March 31, 2016	956,178	2.40	408,388	2.31

The Company recognized a net expense reduction of $95,100 in connection with performance stock unit awards for the three months ended March 31, 2016. The expense reduction was primarily the result of awards that were previously granted to the Company's former Chief Executive Officer that are no longer considered probable of achievement due to the executive's departure in January 2016. Total compensation expense recognized in connection with PSU awards was $35,100 for the three months ended March 31, 2015. Compensation expense recognized for the three months ended March 31, 2016 and 2015 in connection with RSUs was $68,700 and $57,800, respectively.

Shares issued in connection with RSU awards that vested in the three months ended March 31, 2016 and 2015 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 33,150 and 4,779 in the three months ended March 31, 2016 and 2015, 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 $34,476 and $11,277 in the three months ended March 31, 2016 and 2015, 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.

4. Significant Customers and Concentrations of Risk

Revenues by customer location are summarized as follows:

	Three Months Ended March 31,	
	2016	2015
United States of America	$10,570,606	$6,762,776
Europe	1,567,341	1,471,416
Other	180,825	113,845
	$12,318,772	$8,348,037

Significant customers comprising 10% or more of total revenue are as follows:

	Three Months Ended March 31,	
	2016	2015
Teva	$6,485,850	$2,332,815
McKesson [(1)]	1,709,294	1,899,705
Ferring	1,658,622	1,471,416
LEO Pharma	—	857,143
AmerisourceBergen[(1)]	1,147,086	875,145

(1) Represents estimated revenue based on OTREXUP™ shipments, a portion of which has not been recognized as revenue but is recorded in deferred revenue at the end of each period as discussed in Note 2 to the Consolidated Financial Statements.

5. 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 excluded from dilutive loss per share because their effect was anti-dilutive totaled 9,089,499 and 7,500,526 at March 31, 2016 and 2015, respectively.

6. Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016-02, “Leases”, which is intended to increase transparency and comparability among organizations by recognizing all lease transactions (with terms in excess of 12 months) on the balance sheet as a lease liability and a right-of-use asset (as defined). ASU No. 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, with earlier application permitted. Upon adoption, the lessee will apply the new standard retrospectively to all periods presented or retrospectively using a cumulative effect adjustment in the year of adoption. The Company is currently assessing the effect that ASU No. 2016-02 will have on its results of operations, cash flows and financial position.

In March 2016, FASB issued ASU No. 2016-09, “Improvements to Employee Share-Based Payment Accounting”, as part of its simplification initiative. The areas of simplification involve 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. ASU No. 2016-09 is effective for annual and interim periods beginning after December 31, 2016. The Company is currently assessing the impact that the standard will have on its results of operations, cash flows and financial position.

In March 2016, the FASB issued ASU No. 2016-08 “Principal Agent Considerations (Reporting Revenue Gross versus Net)” and in April 2016, FASB issued ASU No. 2016-10 “Identifying Performance Obligations and Licensing.” These updates amend, clarify and provide implementation guidance on the new revenue recognition standard ASU No. 2014-09, Revenue from Contract with Customers, which is effective for annual and interim periods beginning after December 15, 2017. The Company is currently evaluating the impact the adoption of these standards will have on its results of operations, cash flows and financial position.

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," "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 of OTREXUP™ (methotrexate) injection for subcutaneous use;
- our expectations regarding product development including clinical trial results, and potential approval by the United States ("U.S.") Food and Drug Administration ("FDA") of VIBEX® QuickShot Testosterone injection ("VIBEX® QS T");
- our expectations regarding continued product development with Teva Pharmaceutical Industries, Ltd.'s ("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 our and our partner Teva's ability to successfully commercialize and launch VIBEX® Sumatriptan (sumatriptan injection);
- our expectations regarding continued product development with our partners, including Teva and AMAG Pharmaceuticals, Inc. ("AMAG"), and the pursuit of FDA approval of products developed with such partners;
- our expectations regarding trends in pharmaceutical drug delivery characteristics;
- our anticipated continued reliance on contract manufacturers to manufacture our products;
- our sales and marketing plans;
- product development and commercialization plans regarding our other products and product candidates;
- timing and results of our clinical trials;
- our future cash flow and our ability to support our operations;
- the impact of new accounting pronouncements and our expectations and estimates with regard to current accounting practices, including estimates of OTREXUP™ prescription data provided by third-party sources, which are used in our revenue recognition methods; and
- our expectations regarding the year ending December 31, 2016.

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 services or obtain and maintain arrangements with our customers, partners and manufacturers;
- 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, 2015 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 developing and commercializing self-administered parenteral pharmaceutical products and technologies. The Company has multiple internal product development programs as well as numerous partnership arrangements with several industry leading pharmaceutical companies. We have formed strategic alliances with Teva, Ferring Pharmaceuticals Inc. and Ferring B.V. (together "Ferring"), JCR Pharmaceuticals Co., Ltd. ("JCR") and AMAG. We develop and apply our drug delivery systems in collaborations with these pharmaceutical partners to enhance our partners' drug compounds and delivery methods.

We develop and manufacture for ourselves and with partners, novel, pressure-assisted injectors, with and without needles, which allow patients to self-inject drugs. We make a reusable, needle-free spring action injection device which is marketed through our partners for use with human growth hormone ("hGH)". We have developed variations of the needle-free injector by adding a small shielded needle to a pre-filled, single-use disposable injector, called the VIBEX® pressure assisted auto injection system. This system is an alternative to the needle-free system for use with injectable drugs in unit dose containers and is suitable for branded and generic injectables. Additionally, we have developed a disposable multi-dose pen injector for use with standard cartridges, and have a portfolio of gel-based products that are commercialized through various partners.

We launched our product OTREXUP™, which is the first FDA approved subcutaneous methotrexate for once weekly self-administration with an easy-to-use, single dose, disposable auto injector, in February 2014. OTREXUP™ is indicated for adults with severe active rheumatoid arthritis, children with active polyarticular juvenile idiopathic arthritis and adults with severe recalcitrant psoriasis. We previously received FDA approval for dosage strengths of 7.5 mg, 10 mg, 15 mg, 20 mg and 25 mg of OTREXUP™, and recently received FDA approval of three new dosage

strengths (12.5 mg, 17.5 mg and 22.5 mg) in the first quarter of 2016.

Overview of Clinical, Regulatory and Product Development Activities

In December 2015, the FDA approved our Abbreviated New Drug Application (ANDA) for 4 mg/0.5 mL and 6 mg/0.5 mL Sumatriptan Injection USP, indicated for adults for the acute treatment of migraine and cluster headache. Sumatriptan Injection USP represents the Company's first ANDA approval of a complex generic and second product approved using the VIBEX® auto injector platform. Under the terms of a license, supply and distribution arrangement, the VIBEX® Sumatriptan product will be distributed by Teva, and is currently expected to be launched in 2016.

We are collaborating with Teva on a combination product development project for a VIBEX® auto injector pen containing epinephrine. Teva submitted an amendment to the VIBEX® epinephrine pen ANDA in December 2014 and received a Complete Response Letter ("CRL") from the FDA on February 23, 2016 in which, according to Teva, the FDA identified certain major

deficiencies. Teva is evaluating the CRL and intends to submit a response. However, due to the major deficiencies identified in the CRL, Teva expects that its epinephrine product will be substantially delayed from their previously anticipated launch date in the second half of 2016 and that any launch will not take place before 2017.

Our other combination product development projects in collaboration with Teva include a VIBEX® exenatide multi-dose pen, and another previously undisclosed multi-dose pen, which has now been disclosed as 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. Teva also filed an ANDA for teriparatide, which was accepted by the FDA and is currently under review.

We are currently conducting clinical studies of VIBEX® QS T, for testosterone replacement therapy. In February 2015, we announced positive top-line pharmacokinetic results that showed that the primary endpoint was achieved in the Company's ongoing, 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 testosterone deficient adult males. 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 and follow up phase of this study, and in March 2016, we announced the results of the 52 week safety follow-up for the QST 13-003 trial. Based upon a written response we received from the FDA related to our clinical development program for QS T, we are currently conducting an additional study, QST-15-005, to support the filing of our expected 505 (b) (2) New Drug Application ("NDA") for QS T. The study includes 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. We completed enrollment in study QST-15-005 in October 2015 and anticipate that the last patient in the study will complete their final visit in the second quarter of 2016. We expect to file the NDA for QS T in late 2016 or early 2017.

In partnership with AMAG Pharmaceuticals, Inc., we are currently developing a variation of our VIBEX® QuickShot® auto injector for use with AMAG's progestin hormone drug Makena® (hydroxy-progesterone caproate injection) under a license, development and supply agreement. Under this arrangement, AMAG is responsible for the clinical development and preparation, submission and maintenance of all regulatory applications, manufacturing and supplying the drug, and marketing, selling and distributing the final product. We are responsible for the design and development of the auto-injection device, manufacturing and supplying the device, and assembly and packaging of the final product.

Results of Operations

We reported a net loss of $7,656,110 and $6,787,674 for the three months ended March 31, 2016 and 2015, respectively. Operating results for the three months ended March 31, 2016 are not necessarily indicative of the results that may be expected for the year ending December 31, 2016. The following is an analysis and discussion of our operations for the three months ended March 31, 2016 as compared to 2015.

Revenues

	Three months ended March 31,	
	2016	2015
OTREXUP™	$3,309,774	$3,004,309
Needle-free injector devices and components	1,552,385	1,420,753

Auto injector and pen injector devices	5,978,888	198,068
Total product sales	10,841,047	4,623,130
Development revenue	1,098,374	2,388,403
Licensing revenue	50,701	883,009
Royalties	328,650	453,495
Total revenue	$12,318,772	$8,348,037

Total revenue for the three months ended March 31, 2016 and 2015 was $12,318,772 and $8,348,037, respectively, representing an overall growth in total revenue of 48% for the three months ended March 31, 2016 as compared to the same period in the prior year. Below is a detailed discussion of the components of revenue.

OTREXUP™

We sell OTREXUP™ in a package of four pre-filled, single-dose disposable auto injectors to wholesale pharmaceutical distributors, our customers. Sales to our customers are subject to specified rights of return. We currently defer recognition of revenue on product shipments of OTREXUP™ to our customers until the right of return no longer exists, which occurs at the earlier of the time OTREXUP™ units are dispensed through patient prescriptions or expiration of the right of return. Patient prescriptions dispensed are estimated using third-party market prescription data. These third-party sources poll pharmacies, hospitals, mail order and other retail outlets for OTREXUP™ prescriptions and project this sample on a national level. We use this third party prescription data, among other information, as a basis for revenue recognition in each reporting period.

For the three months ended March 31, 2016 and 2015, we recognized $3,309,774 and $3,004,309, respectively, in OTREXUP™ revenue, which is presented net of product sales allowances for estimated wholesaler discounts, prompt pay discounts, chargebacks, rebates and patient discount programs. Sales of OTREXUP™ increased $305,465, or 10% for the three months ended March 31, 2016 as compared with sales in the same period in 2015. We believe the increase in sales is a direct result of an increase in our sales force and marketing efforts.

We had deferred revenue of $834,234 and $1,064,874 at March 31, 2016 and December 31, 2015, respectively, for OTREXUP™ product shipments to wholesalers, which is net of product sales allowances. We will continue to recognize revenue upon the earlier to occur of prescription units dispensed or expiration of the right of return until we can reliably estimate product returns, at which time we will record a one-time increase in net revenue related to the recognition of revenue previously deferred.

Needle-free injector devices and components

Our revenue from reusable needle-free injector devices and disposable components was $1,552,385 and $1,420,753 for the three months ended March 31, 2016 and 2015, respectively. These revenues are generated primarily from sales to Ferring, which sells our needle-free injector with their 4 mg and 10 mg hGH formulations in Europe and Asia. The growth in needle-free device revenue in the three months ended March 31, 2016 as compared to the same period in 2015 is primarily attributable to sales of 5 mg ZOMA-Jet™ needle free devices for use with ZOMACTON™ in the U.S., which was launched by Ferring in the second quarter of 2015.

Auto injector and pen injector devices

Product sales from auto injector and pen injector devices were $5,978,888 and $198,068 for the three months ended March 31, 2016 and 2015, respectively. The significant increase in auto injector sales is principally attributable to pre-launch quantities of auto injector devices sold to Teva for use with their generic epinephrine product, which is currently under FDA review, in anticipation of a potential launch. However, as discussed above, Teva recently received a CRL from the FDA citing certain major deficiencies related to its ANDA for its epinephrine product. As a result, Teva expects that its epinephrine product will be substantially delayed from their previously anticipated launch date in the second half of 2016 and that any launch will not take place before 2017. Accordingly, this delay may impact our sales to Teva. The trend in increased revenue from auto injector devices may not be sustained, and may not be indicative of revenues in future quarters or for the year ending December 31, 2016.

Development revenue

Development revenues typically represent amounts earned under arrangements with partners for which we develop new products on their behalf. Frequently, we receive 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 $1,098,374 and $2,388,403 for the three months ended March 31, 2016 and 2015, respectively. The development revenue recognized for each period presented included revenue recognized upon completion of certain deliverables for the Teva auto injector and pen injector programs, as well as additional development activities for the AMAG auto injector in 2016.

Licensing Revenue

Licensing revenue represents amounts recognized in connection with up-front or milestone payments received from partners that are initially deferred. We recognized $50,701 and $883,009 for the three months ended March 31, 2016 and 2015, respectively. The licensing revenue recognized in 2015 was principally attributable to our license and promotion agreement with LEO Pharma A/S (“LEO”), which was terminated effective June 23, 2015. The upfront and milestone payments received from LEO totaling $10.0 million were being recognized into revenue over a 35-month period. As a result of the termination of the agreement, we recognized the remaining unamortized balance of the deferred revenue in the second quarter of 2015, and no additional revenue related to this arrangement has been or is expected to be recognized in subsequent or future periods, which resulted in the decrease in licensing revenue for the three months ended March 31, 2016 as compared to the same period in 2015.

Royalties

Royalty revenue was $328,650 and $453,495 for the three months ended March 31, 2016 and 2015, respectively. We receive royalties from Ferring related to needle-free injector device sales, from Meda Pharmaceuticals, Inc. on sales of Elestrin® and from Actavis plc on sales of Gelnique 3%®.

Cost of Revenue and Gross Profit

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

	Three months ended March 31,	
	2016	2015
Total revenue	$12,318,772	$8,348,037
Total cost of revenue	6,775,741	3,674,729
Gross profit	$5,543,031	$4,673,308
Gross profit percentage	45 %	56 %

Our gross profit was $5,543,031 for the three months ended March 31, 2016, representing an increase of 19% as compared to the three months ended March 31, 2015. Overall, the increase in our revenues and gross profit is primarily attributable to the increase in sales of pre-launch quantities of our auto injector devices to Teva for use with their generic epinephrine product and an increase in OTREXUP™ sales. These increases were partially offset by the loss of licensing revenue in connection with the termination of the LEO agreement in the second quarter of 2015, which had no associated cost. 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, as discussed in more detail below.

The following table summarizes the revenue, cost of sales and gross margin associated with our product sales:

	Three months ended March 31,	
	2016	2015
Product sales	$10,841,047	$4,623,130
Cost of product sales	6,247,556	1,957,573
Product gross profit	$4,593,491	$2,665,557
Product gross margin percentage	42 %	58 %

The cost of product sales includes product acquisition costs from third-party manufacturers and internal manufacturing overhead expenses. The product gross profit increase in the three months ended March 31, 2016 compared to 2015 was the result of an increase in sales of pre-launch quantities of our auto injector devices to Teva for use with their generic epinephrine product and an increase in sales of OTREXUP™. The reduction in our product gross margin percentage was caused primarily by higher sales of pre-launch quantities of our VIBEX® auto injector for Teva's generic epinephrine product, which has a lower gross margin than OTREXUP™.

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. Development gross profits can vary significantly from period to period depending on the mix of development projects in progress and stages of completion in each period.

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 research and development. Research and development expenses were $5,648,029 and $4,377,981 for the three months ended March 31, 2016 and 2015, respectively, and were primarily related to external expenses incurred in connection with the development of VIBEX® QST for testosterone replacement therapy. The increase in research and development costs are attributable to an increase in external clinical study costs and personnel costs.

Selling, General and Administrative

Selling, general and administrative expenses were $7,603,178 and $7,037,290 for the three months ended March 31, 2016 and 2015, respectively. The increase is attributable to an increase in personnel costs primarily as a result of the growth in our sales force

along with severance costs related to our CEO transition, offset by a reduction in litigation fees which were incurred in the prior year in connection with litigation settled in early 2015.

Liquidity and Capital Resources

At March 31, 2016, our cash and investments totaled $42,111,144, which consisted of $30,102,144 in cash and $12,009,000 in short-term investments. All investments are U.S. Treasury bills or U.S. Treasury notes which we intend to hold to maturity.

We believe that the combination of our current cash and investments balances and projected product sales, product development revenues, milestone payments and royalties will provide us with sufficient funds to support operations. We do not currently have any bank credit lines. If in the future we do not turn profitable or generate cash from operations as anticipated and additional capital is needed to support operations, we may raise additional funds through public or private equity offerings, debt financings or from other sources. We may be unable to obtain such financing, or obtain it on favorable terms, in which case we may be required to curtail development of new products, limit expansion of operations or accept financing terms that are not as attractive as we may desire.

Cash Flows

Net Cash Used in 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, general and administrative costs, research and development projects including clinical studies, and sales and marketing activities. Fluctuations in cash used in operating activities are primarily a result of the timing of cash receipts and disbursement. Net cash used in operating activities was $3,963,806 for the three months ended March 31, 2016 as compared to $10,658,233 for the three months ended March 31, 2015. The decrease in cash used in operating activities in the first quarter of 2016 as compared to 2015 was primarily the result of greater cash used to pay down accounts payable and accrued expenses, and a larger growth in prepaid expenses and receivables, during the first quarter of 2015. For the three months ended March 31, 2016, the net cash used in operating activities was primarily driven by our net loss, adjusted for non-cash operating costs, and offset by the growth in our accounts payable, accrued expenses and deferred costs.

Net Cash Provided by Investing Activities

Net cash provided by investing activities for the three months ended March 31, 2016 was $1,200,504 as compared to $182,754 for the three months ended March 31, 2015, and was attributable to maturities of investment securities of $3,000,000 in each of the periods, as well as timing and amount of capital expenditures. The increase in cash provided by investing activities for the three months ended March 31, 2016 as compared to 2015 was principally due to additional cash payments for patent legal defense costs paid in the first quarter of 2015 in connection with patent litigation that was settled in 2015.

Net Cash Used in Financing Activities

Net cash used in financing activities was $34,476 and $11,277 for the three months ended March 31, 2016 and 2015, respectively, and was related to amounts withheld and remitted to the appropriate taxing authorities for an employee’s minimum statutory obligation for the applicable income and employment taxes in connection with the net settlement of a restricted stock award that vested.

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.

VIBEX® QS T (testosterone). We are developing VIBEX® QS T for self-administered weekly injections of testosterone enanthate in a preservative free formulation for men requiring testosterone replacement.

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 VIBEX® QS T, establishing an agreed upon clinical path forward. In September 2013, we announced that the first patients were dosed in a clinical study evaluating the pharmacokinetics of testosterone enanthate administered weekly by subcutaneous injection at doses of 50 mg and 100 mg via the VIBEX® QS T auto injector device in adult males with testosterone deficiency. The study enrolled 39 patients at nine investigative sites in the U.S. We announced our top-line results of this study on February 20, 2014. The results are considered positive in that VIBEX® QS T treatment resulted in most

patients achieving average levels of testosterone within the normal range from the first dose onward. VIBEX® QS T was also safe and well-tolerated by all dosed patients.

On November 3, 2014, we announced that the last patient has been enrolled in a double-blind, multiple-dose, phase III study (QST-13-003) to evaluate the efficacy and safety of VIBEX® QS T 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 are enrolled in this study. Patients meeting all eligibility criteria were assigned to receive a starting dose of VIBEX® QS T 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 VIBEX® QS T 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 than1500 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 QS T 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 pharmacokinetic sampling, 98.5% were within the pre-defined range. The top-line results are summarized in the table below.

	C_{avg} Lower limit of the 95% 2-sided	C_{avg} % in range 300 – 1100 ng/dL	C_{max} <1500 ng/dL	C_{max} >1800 ng/dL
Population/Analysis	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 (± standard deviation) steady state concentration of testosterone of 553.3 ± 127.3 ng/dL at 12 weeks.

Participants in the study remained on QS T and were followed for an additional 40 weeks for the collection of safety data. On March 16, 2016, we announced that the pharmacokinetic results 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 ≥5%) in this Phase 3 study were increased hematocrit, hypertension, increased PsA, 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. All of the SAE's were not considered to be related to 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), POME, anaphylaxis or major adverse cardiovascular events in this study.

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 QS T. 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 II study, the FDA recommended that we create a larger safety database, including approximately 350 subjects exposed to QS T 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 New Drug Application ("NDA") for QS T 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 QS T 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 May 2015, we received a written update from the FDA related to our clinical development program for QS T. We believe, based on the update received from the FDA, there is an agreed upon path forward for the completion of an additional study to support

the filing of a NDA for QS T. 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 includes 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. The study is a dose-blind, multiple-dose, concentration controlled 26-week supplemental safety and pharmacokinetic study of QuickShot® Testosterone. Patients meeting all eligibility criteria will be assigned to receive 75 mg of QS T once weekly for six weeks. According to the protocol, adjustments to dose may be made at week seven based upon the week six C_{trough} value. QS T will be provided to clinical sites at dosage strengths of 100 mg, 75 mg and 50 mg to be utilized in dose titration.

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 early November 2015, the Company also announced that enrollment was complete in study QST-15-005. At that time, 108 patients had received a dose of QS T. Following completion of screening, 133 patients were dosed with QS T. The Company believes that upon successful completion of this study we should be able to satisfy the FDA's recommendation for the larger safety database as discussed above. We anticipate the last patient in the QST-15-005 study will complete their final visit in the second quarter of 2016.

In addition to the clinical trial program, there is an ongoing Human Factors program to demonstrate safe and reliable at-home usability of QS T. Study populations include trained and untrained subjects, including patients, non-patient caregivers and health care providers. The goals of the program are to optimize and document reliable and proper administration in study subjects in the setting of at-home use in order to support the approvability of the product.

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, our QuickShot® ("QS") 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 a product containing sumatriptan as well as for our pen injector devices for a product containing exenatide and a product containing teriparatide. We also have a license, development and supply agreement with AMAG for our QS device containing Makena® indicated for reduced risk of preterm birth. Our pressure assisted auto injectors are designed to deliver drugs by injection from single dose prefilled syringes. The disposable pen injector device is designed to deliver drugs by injection through needles from multi-dose cartridges. 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 equipment. The following is a summary of the development stage for the four products in development with Teva and the development stage of our product with AMAG.

VIBEX® with Epinephrine

We have designed the VIBEX® device for a product containing epinephrine and have scaled up the commercial tooling and molds for this product. From a regulatory standpoint Teva filed this product as an ANDA, and the FDA accepted the filing as such. Currently, Teva is conducting its own development work on the drug product (epinephrine). An amendment to the ANDA was filed with the FDA in December 2014. Teva received a complete response letter on February 23, 2016 relating to its epinephrine ANDA in which, according to Teva, the FDA identified certain major deficiencies. Teva is evaluating the CRL and intends to submit a response. Due to the major deficiencies identified in the CRL, Teva expects that its epinephrine product will be substantially delayed from the previously anticipated launch date in the second half of 2016 and that any launch will not take place before 2017.

VIBEX® with Sumatriptan

We have designed the VIBEX® device for a product containing sumatriptan and have scaled up the commercial tooling and molds for this product. In December 2015, the FDA approved our ANDA for 4 mg/0.5 mL and 6 mg/0.5 mL Sumatriptan Injection USP, indicated for adults for the acute treatment of migraine and cluster headache. 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 VIBEX® Sumatriptan product will be distributed under the terms of a license, supply and distribution arrangement with Teva, and is currently expected to be launched in 2016.

Teriparatide disposable pen injector

We have developed, produced and provided clinical supplies for a previously undisclosed pen injector product, which was referred to as "Pen 1". In April 2016, we disclosed that the "Pen 1" project with Teva relates to a generic form of Forteo® (teriparatide [rDNA origin] injection) ("Teriparatide"), marketed by Eli Lilly and Company ("Lilly"). Forteo® is an injectable treatment for osteoporosis in postmenopausal women and men at high risk for fracture and for glucocorticoid induced osteoporosis in men and postmenopausal women. Teva previously filed an ANDA for Teriparatide, which was accepted by the FDA and is currently under review. On March 16, 2016, Lilly filed a lawsuit against Teva alleging patent infringement in response to Teva's Paragraph IV notice

and filing contained in their ANDA for Teriparatide, resulting in a thirty-month stay on FDA's approval of the ANDA. The stay will expire in August 2018 unless the litigation is resolved prior to that time. Based on available information, we believe that Teva may be the "first applicant" to file an ANDA for a generic equivalent of Forteo® and, should Teva's ANDA be approved, may be entitled to 180 days of generic market exclusivity. The ANDA for Teriparatide represents the fourth ANDA for which the Company is the device developer and the third drug device combination product with first-to-file status using one of our devices.

Exenatide disposable pen injector

We have designed and produced pen injectors for the exenatide pen injector product ("Exenatide"). Teva initiated drug stability and completed the device development program and filed an ANDA with the FDA in the second half of 2013. The ANDA was accepted by the FDA in October 2014 and is currently under FDA review. In December 2014, Amylin Pharmaceuticals Inc. and AstraZeneca plc filed a complaint alleging patent infringement against Teva resulting in a thirty-month stay on FDA's approval of the ANDA; the stay will expire in April 2017 unless the litigation is resolved prior to that time. Based on available information, we believe that Teva may be the "first applicant" to file an ANDA for Exenatide as a generic equivalent of Byetta® and, should Teva's ANDA be approved, may be entitled to 180 days of generic market exclusivity.

VIBEX® QS with Makena® (hydroxyprogesterone caproate injection)

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.

Other Research and Development Costs. In addition to the VIBEX® QS T project and the Teva and AMAG related device development projects, we incur direct costs in connection with other research and development projects related to our technologies and indirect costs that include personnel costs, administrative and other operating costs related to managing our research and development projects.

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.

Critical Accounting Policies

We have identified certain of our significant accounting policies that we consider particularly important to the portrayal of our results of operations and financial position and which may require the application of a higher level of judgment by management and, as a result, are subject to an inherent level of uncertainty. These policies are characterized as "critical accounting policies" and address revenue recognition, inventory valuation, valuation of long-lived and intangible assets, and share-based compensation and are more 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, 2015.

Recently Issued Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, "Leases", which is intended to increase transparency and comparability among organizations by recognizing

all lease transactions (with terms in excess of 12 months) on the balance sheet as a lease liability and a right-of-use asset (as defined). ASU No. 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, with earlier application permitted. Upon adoption, the lessee will apply the new standard retrospectively to all periods presented or retrospectively using a cumulative effect adjustment in the year of adoption. We are currently assessing the effect that ASU No. 2016-02 will have on our results of operations, cash flows and financial position.

In March 2016, FASB issued ASU No. 2016-09, “Improvements to Employee Share-Based Payment Accounting”, as part of its simplification initiative. The areas of simplification involve 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. ASU No. 2016-09 is effective for annual and interim periods beginning after December 31, 2016. We are currently assessing the impact that the standard will have on our results of operations, cash flows and financial position.

In March 2016, the FASB issued ASU No. 2016-08 “Principal Agent Considerations (Reporting Revenue Gross versus Net)” and in April 2016, FASB issued ASU No. 2016-10 “Identifying Performance Obligations and Licensing.” These updates amend, clarify and provide implementation guidance on the new revenue recognition standard ASU No. 2014-09, Revenue from Contract with Customers, which is effective for annual and interim periods beginning after December 15, 2017. We are currently evaluating the impact the adoption of these standards will have on our results of operations, cash flows and financial position.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our primary market risk exposure is 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 March 31, 2016 was not material.

We also have limited exposure to market risk due to interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because a significant portion of our investments are in debt securities issued by the U.S. government and institutional money market funds. The primary objective of our investment activities is to preserve principal. To minimize market risk, we have in the past and, to the extent possible, will continue in the future, to hold debt securities to maturity at which time the debt security will be redeemed at its stated or face value. Due to the nature of our marketable securities, we believe that we are not exposed to any material market interest rate risk related to our investment portfolio.

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, 2015, 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.

Risks Related to our Common Stock

Our common stock is listed on The NASDAQ Capital Market and if we do not maintain compliance with NASDAQ Marketplace Rules our common stock may be delisted from the NASDAQ Capital Market.

To keep our listing on The NASDAQ Capital Market, we are required to maintain: (i) a minimum bid price of $1.00 per share, (ii) a certain public float, (iii) a certain number of round lot shareholders and (iv) one of the following: a net income from continuing operations (in the latest fiscal year or two of the three last fiscal years) of at least $500,000, a market value of listed securities of at least $35 million or a stockholders’ equity of at least $2.5 million. On April 12, 2016, we were notified by the NASDAQ Listing Qualifications Department that we do not comply with the $1.00 minimum bid threshold as our common stock has traded below the $1.00 minimum bid price for 30 consecutive business days. We were automatically provided with a 180-calendar day period within which to regain compliance. To regain compliance, our common stock must close at or above the $1.00 minimum bid price for at least 10 consecutive days or more at the discretion of NASDAQ.

We are also required to maintain certain corporate governance requirements. In the event that in the future we are notified that we no longer comply with NASDAQ’s corporate governance requirements, and we fail to regain compliance within the applicable cure period, our common stock could be delisted from The NASDAQ Capital Market.

If our common stock is delisted, trading of the stock will most likely take place on an over-the-counter market established for unlisted securities, such as the Pink Sheets or the OTC Bulletin Board. An investor is likely to find it less convenient to sell, or to obtain accurate quotations in seeking to buy, our common stock on an over-the-counter market, and many investors may not buy or sell our common stock due to difficulty in accessing over-the-counter markets, or due to policies preventing them from trading in securities not listed on a national exchange or other reasons. For these reasons and others, delisting would adversely affect the liquidity, trading volume and price of our common stock, causing the value of an investment in us to decrease and having an adverse effect on our business, financial condition and results of operations, including our ability to attract and retain qualified executives and employees and to raise capital.

If our common stock is delisted from The NASDAQ Capital Market, we may be subject to the risks relating to penny stocks.

If our common stock were to be delisted from trading on The NASDAQ Capital Market and the trading price of the common stock were below $5.00 per share on the date the common stock was delisted, trading in our common stock

would also be subject to the requirements of certain rules promulgated under the Exchange Act. These rules require additional disclosure by broker-dealers in connection with any trades involving a stock defined as a “penny stock” and impose various sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors, generally institutions. These additional requirements may discourage broker-dealers from effecting transactions in securities that are classified as penny stocks, which could severely limit the market price and liquidity of such securities and the ability of purchasers to sell such securities in the secondary market. A penny stock is defined generally as any non-exchange listed equity security that has a market price of less than $5.00 per share, subject to certain exceptions.

Item 2. UNREGISTERED SALE OF EQUITY SECURITIES AND USE OF PROCEEDS
None.
Item 3. DEFAULT UPON SENIOR SECURITIES
None.
Item 4. MINE SAFETY DISCLOSURES
Not applicable.
Item 6. EXHIBITS
(a) Exhibit Index

Exhibit No.	Description
10.1#	Employment Agreement dated as of March 4, 2016 between Antares Pharma, Inc. and Robert F. Apple
31.1#	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.
31.2#	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.
32.1##	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.
32.2##	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.
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.

May 9, 2016 /s/ Robert F. Apple
Robert F. Apple
President and Chief Executive Officer
(Principal Executive Officer)

May 9, 2016 /s/ James E. Fickenscher
James E. Fickenscher
Senior Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)