

ANTARES PHARMA, INC.  
Form 10-Q  
May 09, 2014  
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**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, 2014**

**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, 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   
Non-accelerated filer  (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  No

The number of shares outstanding of the registrant's Common Stock, \$.01 par value, as of May 1, 2014 was 130,006,518.

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**Table of Contents****PART I FINANCIAL INFORMATION***Item 1. FINANCIAL STATEMENTS***ANTARES PHARMA, INC.****CONSOLIDATED BALANCE SHEETS**

	<b>March 31, 2014 (Unaudited)</b>	<b>December 31, 2013</b>
<b>Assets</b>		
Current Assets:		
Cash and cash equivalents	\$ 39,057,450	\$ 39,067,236
Short-term investments	21,002,297	24,014,305
Accounts receivable	3,648,162	1,034,492
Inventories	7,106,012	6,461,051
Deferred costs	545,032	375,773
Prepaid expenses and other current assets	996,536	1,706,678
<b>Total current assets</b>	<b>72,355,489</b>	<b>72,659,535</b>
Equipment, molds, furniture and fixtures, net	7,632,001	6,952,251
Patent rights, net	2,124,789	1,345,177
Goodwill	1,095,355	1,095,355
Long-term investments	3,005,066	6,008,169
Other assets	871,460	871,444
<b>Total Assets</b>	<b>\$ 87,084,160</b>	<b>\$ 88,931,931</b>
<b>Liabilities and Stockholders Equity</b>		
Current Liabilities:		
Accounts payable	\$ 5,679,990	\$ 6,378,712
Accrued expenses and other liabilities	5,428,622	5,453,075
Deferred revenue	6,182,342	4,531,220
<b>Total current liabilities</b>	<b>17,290,954</b>	<b>16,363,007</b>
Deferred revenue long term	5,978,654	1,855,196
<b>Total liabilities</b>	<b>23,269,608</b>	<b>18,218,203</b>
Stockholders Equity:		
Preferred Stock: \$0.01 par, authorized 3,000,000 shares, none outstanding		
Common Stock: \$0.01 par; authorized 200,000,000 shares; 129,938,018 and 128,740,604 issued and outstanding at March 31, 2014 and December 31, 2013, respectively	1,299,380	1,287,406
Additional paid-in capital	245,256,729	243,375,465

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Accumulated deficit	(182,090,546)	(173,295,941)
Accumulated other comprehensive loss	(651,011)	(653,202)
	63,814,552	70,713,728
<b>Total Liabilities and Stockholders Equity</b>	<b>\$ 87,084,160</b>	<b>\$ 88,931,931</b>

See accompanying notes to consolidated financial statements.

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**ANTARES PHARMA, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(UNAUDITED)**

	<b>For the Three Months Ended March 31,</b>	
	<b>2014</b>	<b>2013</b>
Revenue:		
Product sales	\$ 1,805,302	\$ 2,492,476
Development revenue	1,421,149	793,710
Licensing revenue	928,129	69,345
Royalties	1,047,615	1,172,691
Total revenue	5,202,195	4,528,222
Cost of revenue:		
Cost of product sales	1,017,437	1,427,641
Cost of development revenue	159,308	599,502
Total cost of revenue	1,176,745	2,027,143
Gross profit	4,025,450	2,501,079
Operating expenses:		
Research and development	4,533,626	3,072,685
Sales and marketing	5,510,202	881,253
General and administrative	2,789,966	1,950,430
Total operating expenses	12,833,794	5,904,368
Operating loss	(8,808,344)	(3,403,289)
Other income (expense)	13,739	(5,159)
Net loss	\$ (8,794,605)	\$ (3,408,448)
Basic and diluted net loss per common share	\$ (0.07)	\$ (0.03)
Basic and diluted weighted average common shares outstanding	129,656,257	126,106,713

See accompanying notes to consolidated financial statements.

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**ANTARES PHARMA, INC.**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**  
**(UNAUDITED)**

	<b>For the Three Months Ended March 31,</b>	
	<b>2014</b>	<b>2013</b>
Net loss	\$ (8,794,605)	\$ (3,408,448)
Foreign currency translation adjustment	2,191	(19,355)
Comprehensive loss	\$ (8,792,414)	\$ (3,427,803)

See accompanying notes to consolidated financial statements.

**Table of Contents****ANTARES PHARMA, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS****(UNAUDITED)**

	<b>For the Three Months Ended March 31,</b>	
	<b>2014</b>	<b>2013</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (8,794,605)	\$ (3,408,448)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation and amortization	224,753	74,618
Stock-based compensation expense	621,427	451,276
Amortization of premiums and discounts	15,111	60,087
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable	(2,613,670)	499,418
Inventories	(644,961)	294,873
Prepaid expenses and other current assets	710,206	(204,098)
Deferred costs	(169,259)	(147,108)
Other assets	(17)	(11,844)
Accounts payable	(1,144,516)	307,521
Accrued expenses and other current liabilities	(939,596)	(1,155,935)
Deferred revenue	5,774,239	(803,503)
<b>Net cash used in operating activities</b>	<b>(6,960,888)</b>	<b>(4,043,143)</b>
<b>Cash flows from investing activities:</b>		
Purchases of equipment, molds, furniture and fixtures	(128,701)	(763,600)
Additions to patent rights	(42,259)	(38,100)
Proceeds from maturities of investment securities	6,000,000	
Purchases of investment securities		(9,118,161)
<b>Net cash provided by (used in) investing activities</b>	<b>5,829,040</b>	<b>(9,919,861)</b>
<b>Cash flows from financing activities:</b>		
Proceeds from exercise of stock options and warrants	1,236,935	103,069
Taxes paid related to net share settlement of equity awards	(115,123)	(104,329)
<b>Net cash provided by (used in) financing activities</b>	<b>1,121,812</b>	<b>(1,260)</b>
<b>Effect of exchange rate changes on cash and cash equivalents</b>	<b>250</b>	<b>(6,745)</b>
<b>Net decrease in cash and cash equivalents</b>	<b>(9,786)</b>	<b>(13,971,009)</b>
<b>Cash and cash equivalents:</b>		



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Beginning of period	39,067,236	52,097,064
End of period	\$ 39,057,450	\$ 38,126,055

Noncash investing activities:

Purchases of equipment, molds, furniture and fixtures recorded in accounts payable and accrued expenses	\$ 739,713	\$
Additions to patent rights recorded in accounts payable and accrued expenses	771,100	

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. (the Company or Antares) is an emerging specialty pharmaceutical company that focuses on developing and commercializing self-administered parenteral pharmaceutical products and technologies. The Company has numerous partnerships with pharmaceutical companies as well as multiple internal product development programs. The Company has developed both subcutaneous and intramuscular injection technology systems which include Vibex® disposable pressure-assisted auto injectors, reusable needle-free injectors, and disposable multi-use pen injectors.

On October 14, 2013, the Company announced the approval of OTREXUP (methotrexate) injection by the FDA, and in January 2014 announced the launch of OTREXUP and in February began detailing the product to health care professionals. OTREXUP is the first FDA approved subcutaneous methotrexate for once weekly self-administration with an easy-to-use, single dose, disposable auto injector. OTREXUP is indicated for adults with severe active rheumatoid arthritis (RA) or children with active polyarticular juvenile idiopathic arthritis and adults with severe recalcitrant psoriasis. The Company has worldwide marketing rights for OTREXUP. The Company will commercialize OTREXUP in the U.S. for the treatment of RA and has provided LEO Pharma the exclusive right to commercialize OTREXUP in the U.S. for the treatment of psoriasis.

The Company is also developing Vibex® QS T for testosterone replacement therapy for men suffering from symptomatic testosterone deficiency. In February 2014 the Company announced positive top line results from a clinical study evaluating the PK 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 hypogonadal adult males. The study enrolled 39 patients at nine investigative sites in the United States. 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. The Company intends to begin a Phase 3 clinical study in 2014 to validate the results in a larger group of hypogonadal men over an extended period of at-home weekly dosing.

The Company has licensed its reusable needle-free injection device for use with human growth hormone (hGH) to Teva Pharmaceutical Industries, Ltd. (Teva), Ferring Pharmaceuticals BV (Ferring) and JCR Pharmaceuticals Co., Ltd. (JCR), with Teva and Ferring being two of the Company's primary customers. The Company's needle-free injection device is marketed by Teva as the Tjet® injector system to administer their 5mg Tev-Tropin® brand hGH marketed in the U.S. The Company's needle-free injection device is marketed by Ferring with their 4mg and 10mg hGH formulations as Zomajet® 2 Vision and Zomajet® Vision X, respectively, in Europe and Asia. The Company has also licensed both disposable auto and pen injection devices to Teva for use in certain fields and territories and is engaged in product development activities for Teva utilizing these devices.

The Company also has a portfolio of gel-based products. Gelnique 3%, the Company's topical oxybutynin gel product for the treatment of overactive bladder (OAB), which was approved by the FDA in December 2011, is currently being marketed by Actavis plc in the U.S. The Company has also entered into a licensing agreement with Daewoong Pharmaceuticals under which Daewoong will commercialize this product, once approved in South Korea. The

Company's gel portfolio also includes Elestri<sup>®</sup> (estradiol gel) currently marketed by Meda Pharma in the U.S. for the treatment of moderate-to-severe vasomotor symptoms associated with menopause.

The Company has two facilities in the U.S. The Parenteral Products Group located in Minneapolis, Minnesota directs the manufacturing and marketing of the Company's reusable needle-free injection devices and related disposables, and develops its disposable pressure-assisted auto injector and pen injector systems. The Company's corporate head office, Product Development Group and Commercial Group are located in Ewing, New Jersey, where the Product Development Group directs the clinical, regulatory and commercial development of the Company's internal drug/device combination products. The Commercial Group is responsible for sales, marketing, medical affairs, trade and third party reimbursement for internally developed products.

**Table of Contents****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 United States of America 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 United States of America 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 should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended December 31, 2013. Operating results for the three months ended March 31, 2014 are not necessarily indicative of the results that may be expected for the year ending December 31, 2014.

Certain prior year amounts have been reclassified in the consolidated financial statements to conform to the current year presentation. These reclassifications were made to present sales and marketing as a separate line item as the Company commences commercialization of OTREXUP<sup>®</sup>. Business development expenses previously included within sales, marketing and business development have been reclassified to general and administrative expense. These reclassifications had no effect on previously reported net income or total operating expenses.

*Investments*

All short-term and long-term investments are U.S. Treasury bills or U.S. Treasury notes that are classified as held-to-maturity because the Company has the positive intent and ability to hold the securities to maturity. The securities are carried at their amortized cost. The fair value of all securities is determined by quoted market prices. All long-term investments mature in less than two years. At March 31, 2014 the short-term investments had a fair value of \$21,009,939 and a carrying value of \$21,002,297 and the long-term investments had a fair value of \$3,007,851 and a carrying value of \$3,005,066. At December 31, 2013 the short-term investments had a fair value of \$24,021,522 and a carrying value of \$24,014,305 and the long-term investments had a fair value of \$6,007,851 and a carrying value of \$6,008,169.

*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 and assembly operations are outsourced to third-party suppliers 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. Inventories consist of the following:

	<b>March 31, 2014</b>	<b>December 31, 2013</b>
<b>Inventories:</b>		
Raw material	\$ 1,109,480	\$ 1,056,054
Work in process	2,782,614	3,034,321
Finished goods	3,213,918	2,370,676
	<b>\$ 7,106,012</b>	<b>\$ 6,461,051</b>

*Capitalized Patent Costs*

The Company capitalizes external legal patent defense costs and costs for pursuing patent infringements when it determines that a successful outcome is probable and will lead to an increase in the value of the patent. The capitalized costs will be amortized over the remaining life of the related patent. If changes in the anticipated outcome were to occur that reduce the likelihood of a successful outcome of the entire action to less than probable, the capitalized costs would be charged to expense in the period in which the change is determined. As of March 31, 2014 and December 31, 2013, \$0.9 million and \$0.1 million of external legal patent costs were capitalized, respectively.

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In February 2014, the Company began detailing OTREXUP<sup>®</sup> to health care professionals in the United States 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<sup>®</sup>, the Company currently cannot reliably estimate expected returns of the product at the time of shipment. Accordingly, the Company defers recognition of revenue on product shipments of OTREXUP<sup>®</sup> until the right of return no longer exists, which occurs at the earlier of the time OTREXUP<sup>®</sup> 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. The Company estimates patient prescriptions dispensed using third-party market prescription data. The Company does not have significant history estimating the number of patient prescriptions dispensed. If the Company underestimates or overestimates patient prescriptions dispensed for a given period, adjustments to revenue may be necessary in future periods.

The Company recognized \$212,845 in OTREXUP<sup>®</sup> product revenue from U.S. customers for the three months ended March 31, 2014, which is net of estimated wholesaler discounts, prompt pay discounts, chargebacks, rebates and patient discount programs. The Company had a deferred revenue balance of \$2,103,507 at March 31, 2014 for OTREXUP<sup>®</sup> product shipments, which is net of estimated wholesaler discounts, prompt pay discounts, chargebacks, rebates and patient discount programs.

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<sup>®</sup> 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.

*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 the Company's 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, the Company may need to adjust these estimates, which could have an effect on product revenue in the period of adjustment. The Company's product sales allowances include:

*Wholesaler Distribution Fees.* The Company pays distribution fees 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.* Through March 31, 2014, the Company has not been subject to any chargebacks. However, in the future, the Company expects to provide discounts primarily 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.

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These entities will purchase products from the wholesale distributors at a discounted price, and the wholesale distributors will 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 will estimate and accrue chargebacks based on estimated wholesaler inventory levels, current contract prices and historical chargeback activity. Chargebacks will be 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, including Medicare and Medicaid programs. 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 future 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. Stockholders Equity***Stock Options, Stock Awards and Warrants*

The Company records compensation expense associated with share based awards granted to employees at the fair value of the award on the date of grant. The expense is recognized over the period during which an employee is required to provide services in exchange for the award.

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. Under the Plan, the maximum number of shares authorized for issuance is 15,000,000 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 either 10 (for US employees) or 11 (for Swiss employees) years and the options vest in varying periods. As of March 31, 2014, the Plan had 279,620 shares available for grant. Stock option exercises are satisfied through the issuance of new shares.

A summary of stock option activity under the Plan as of March 31, 2014, and the changes during the three months then ended is as follows:

	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Term (Years)</b>	<b>Aggregate Intrinsic Value (\$)</b>
<b>Number of Shares</b>			



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		(\$)		
Outstanding at December 31, 2013	7,697,892	1.89		
Granted	17,500	4.45		
Exercised	(570,178)	1.21		2,057,025
Cancelled/Forfeited	(7,500)	4.45		
 Outstanding at March 31, 2014	 7,137,714	 1.95	 6.5	 11,756,129
 Exercisable at March 31, 2014	 5,834,951	 1.56	 5.9	 11,496,000

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Total recognized compensation expense for stock options was approximately \$360,000 and \$260,000 for the first three months of 2014 and 2013, respectively. As of March 31, 2014, there was approximately \$2,200,000 of total unrecognized compensation cost related to nonvested outstanding stock options that is expected to be recognized over a weighted average period of approximately 1.9 years.

The per share weighted average fair value of options granted during the first three months of 2014 was estimated as \$2.55 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. There were no options granted in the first three months of 2013.

	<b>March 31, 2014</b>
Risk-free interest rate	1.7%
Annualized volatility	61.7%
Weighted average expected life, in years	6.0
Expected dividend yield	0.0%

In the first three months of 2014, 570,178 stock options with a weighted average exercise price of \$1.21 were exercised which generated proceeds of \$691,935 to the Company. In the first three months of 2013, 78,417 stock options with a weighted average exercise price of \$0.64 were exercised which generated proceeds of \$50,246 to the Company.

*Stock Awards*

At times, the Company makes discretionary grants of its common stock to members of management and other employees in lieu of cash bonus awards or in recognition of special achievements. In the first quarter of 2014 there were 150,000 shares of common stock granted to members of executive management as bonus compensation for achievements in 2013. There were no discretionary grants of common stock in 2013.

Expense is recognized on a straight line basis over the vesting period and is based on the fair value of the stock on the grant date. The fair value of each stock award is determined based on the number of shares granted and the market price of the Company's common stock on the date of grant.

In addition to the shares granted to members of management and employees, at times directors receive a portion of their annual compensation in shares of Company common stock. Expense is recognized on a straight line basis over the one year period that the compensation is earned. Expense recognized in connection with shares granted to directors was \$179,600 and \$182,800 in the three month periods ended March 31, 2014 and 2013, respectively.

As of March 31, 2014, a total of 212,618 shares granted to directors were unvested. As of March 31, 2014, there was approximately \$142,000 of total unrecognized compensation cost related to nonvested stock awards that is expected to be recognized over a weighted average period of approximately 2 months. The weighted average fair value of the shares granted in 2014 and 2013, excluding shares granted under the LTIP program, was \$4.58 and \$4.01 per share, respectively.

*Long Term Incentive Program (LTIP)*

The Company's Board of Directors has approved a long term incentive program for the benefit of the Company's senior executives. Pursuant to the long term incentive program, the Company's senior executives have been awarded stock options and performance stock units with targeted values based on values granted by the Company's peer group. In 2013, the program was modified such that the value of the annual award for each senior executive was delivered one-third in the form of performance stock units, one-third in the form of shares of restricted stock and one-third in the form of stock options. In prior years,

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two thirds of the value for each senior executive was delivered in the form of stock options and one third of the value was delivered in the form of performance stock units. 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 restricted stock vests in three equal annual installments. Expense recognized in the first quarter of 2014 in connection with the restricted stock was approximately \$51,000. The performance stock unit awards made to the senior executives will be vested and convert into actual shares of the Company's common stock based on the Company's attainment of certain performance goals over a performance period of three years. Expense recognized in the first quarter of 2014 in connection with the performance stock unit awards for defined performance goals considered probable of achievement was \$31,000. The performance stock unit awards and restricted stock granted under the long term incentive program are summarized in the following table:

	Performance Stock		Restricted Stock	
	Number of Shares	Weighted Average Fair Value (\$)	Number of Shares	Weighted Average Fair Value (\$)
Outstanding at December 31, 2013	406,663	3.19	155,724	3.96
Granted				
Vested	(75,000)	1.66		
Forfeited/Expired	(75,000)	1.66		
Outstanding at March 31, 2014	256,663	3.19	155,724	3.96

A portion of the shares that were granted as discretionary shares or under the LTIP program that vested in the first quarters of 2014 and 2013 were net-share settled such that the Company withheld shares with 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 were 25,545 and 30,153 in 2014 and 2013, respectively, and were based on the 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 \$115,123 and \$104,329 in 2014 and 2013, 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.

*Warrants*

In the first three months of 2014, the Company received proceeds of \$545,000 from the exercise of 545,000 warrants with an exercise price of \$1.00. In the first three months of 2013, the Company received proceeds of \$52,823 from the exercise of 52,823 warrants with an exercise price of \$1.00. There were 100 and 545,100 warrants outstanding at March 31, 2014 and December 31, 2013, respectively.

**4. 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 warrants excluded from dilutive loss per share because their effect was anti-dilutive totaled 7,137,814 and 10,697,415 at March 31, 2014 and 2013, respectively. The table below discloses the basic and diluted loss per common share.

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2014</b>	<b>2013</b>
Net loss	\$ (8,794,605)	\$ (3,408,448)
Basic and diluted weighted average common shares outstanding	129,656,257	126,106,713
Basic and diluted net loss per common share	\$ (0.07)	\$ (0.03)

**Table of Contents****5. Industry Segment and Operations by Geographic Areas**

The Company has one operating segment, drug delivery, which includes the development of injection devices and injection based pharmaceutical products as well as transdermal gel products.

Revenues by customer location are summarized as follows:

	<b>Three Months Ended March 31,</b>	
	<b>2014</b>	<b>2013</b>
United States of America	\$ 3,914,659	\$ 3,527,287
Europe	1,085,096	933,639
Other	202,440	67,296
	<b>\$ 5,202,195</b>	<b>\$ 4,528,222</b>

Revenues by product type:

	<b>Three Months Ended March 31,</b>	
	<b>2014</b>	<b>2013</b>
Injection products	\$ 4,806,782	\$ 3,436,500
Transdermal gel products	395,413	1,091,722
	<b>\$ 5,202,195</b>	<b>\$ 4,528,222</b>

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

	<b>Three Months Ended March 31,</b>	
	<b>2014</b>	<b>2013</b>
Teva	\$ 2,448,287	\$ 2,455,266
Ferring	1,085,096	933,639
LEO Pharma	857,143	
Actavis	166,627	874,328

**6. License Agreements***LEO Pharma Promotion and License Agreement*

In November 2013 the Company entered into a promotion and license agreement with LEO Pharma ( LEO ). Under this agreement the Company granted LEO the exclusive right to promote OTREXUP to dermatologists for symptomatic control of severe recalcitrant psoriasis in adults in the U.S. LEO is responsible for promotion and marketing activities

in dermatology and the Company is responsible for the supply of OTREXUP product and samples. The Company received from LEO a non-refundable upfront payment of \$5.0 million, a milestone payment of \$5.0 million and will receive a milestone payment of \$10.0 million upon realizing a defined level of net sales in a calendar year. The Company will pay LEO a percentage of net sales generated in dermatology and will record the payments to LEO as sales and marketing expense.

The Company identified and evaluated a number of deliverables in the agreement and concluded that none of the deliverables have value on a stand-alone basis. As a result, these deliverables do not qualify for treatment as separate units of accounting. Accordingly, the deliverables have been accounted for as a single unit of accounting and each of the payments will be allocated to these deliverables and will be recognized as revenue over the 35 month estimated life of the agreement. The Company recognized revenue of approximately \$857,000 in the three months ended March 31, 2014, and recorded deferred revenue of \$8,571,000 at March 31, 2014 in connection with this agreement.

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**Table of Contents****7. New Accounting Pronouncements**

In July 2013, the FASB issued Accounting Standards Update 2013-11, Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists (ASU 2013-11). ASU 2013-11 amends accounting guidance on the presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or tax credit carryforward exists. This new guidance requires entities, if certain criteria are met, to present an unrecognized tax benefit, or portion of an unrecognized tax benefit, in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward when such items exist in the same taxing jurisdiction. The adoption of ASU 2013-11 is expected to reduce diversity in practice by providing guidance on the presentation of unrecognized tax benefits. The provisions of ASU 2013-11 are effective for fiscal years and interim periods beginning after December 15, 2013. The adoption of this update in the first quarter of 2014 did not have a material effect on the Company's consolidated financial statements.

**8. Legal Proceedings**

In the first quarter of 2014 Medac Pharma announced that it submitted an NDA to the FDA for an auto-pen containing methotrexate. On February 28, 2014, Antares filed a complaint against Medac Pharma and Medac GmbH (Medac GmbH, together with Medac Pharma, Medac), the parent company of Medac Pharma, in the United States District Court for the District of Delaware, alleging infringement of two of the Company's patents for technology regarding an auto-injector and an auto-injector containing methotrexate. The complaint asserts that Medac Pharma's NDA submission infringes, that Medac Pharma's proposed product will infringe the Company's patents, and that Medac Pharma should be enjoined from marketing its product. During the three months ended March 31, 2014, a total of approximately \$720,000 in legal costs in connection with this suit have been capitalized. However, there is no assurance of success with any patent litigation, and it could be costly and time consuming and depending on the ultimate outcome of the litigation may have an adverse effect on results of operations and OTREXUP market penetration. If the Company determines that the likelihood of a successful outcome of the entire action changes and becomes less than probable, the capitalized costs would be charged to expense in the period in which the change is determined.

On March 7, 2014, Medac filed suit against Antares, LEO Pharma and its parent company LEO Pharma A/S (together, the LEO Entities) in the United States District Court for the District of New Jersey, alleging that Antares and the LEO Entities infringe Medac's U.S. Patent 8,664,231 (the 231 patent) that was issued by the U.S. Patent and Trademark Office on March 4, 2014. The complaint states that the 231 patent relates to a concentration of more than 30mg/mL. Medac alleges that OTREXUP infringes the 231 patent, and demands that Antares and the LEO Entities be enjoined from making, using, selling, importing or offering OTREXUP and pay unspecified amounts of compensatory damages, treble damages and attorneys' fees. The Company intends to defend itself vigorously. Under the terms of the promotion and license agreement between the Company and the LEO Entities, the Company agreed to indemnify the LEO Entities from claims that OTREXUP infringes the intellectual property rights of any third party. Legal costs in connection with this suit are expensed as incurred.



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

**Forward-Looking Statements**

Management's discussion and analysis of the significant changes in the consolidated results of operations, financial condition and cash flows of the Company is set forth below. Certain statements in this report may be considered to be forward-looking statements as that term is defined in the U.S. Private Securities Litigation Reform Act of 1995, such as statements that include the words expect, estimate, project, anticipate, should, intend, probability, risk, objective and 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 (Vibe<sup>®</sup> MTX);

our expectations regarding product development of Vibex<sup>®</sup> QS T;

our expectations regarding continued product development with Teva;

our plans regarding potential manufacturing and marketing partners;

our future cash flow;

the outcome of our pending litigation;

the impact of new accounting pronouncements; and

our expectations regarding the year ending December 31, 2014.

The words may, will, expect, intend, anticipate, estimate, believe, continue, and similar expressions may be used in this report to identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements involve known and unknown risks, uncertainties and achievements, 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 patent litigation;

our inability to attract and retain key personnel;

adverse economic and political conditions; and

our inability to obtain additional financing, reduce expenses or generate funds when necessary.

In addition, you should refer to the Risk Factors section of our Annual Report on Form 10-K for the year ended December 31, 2013 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.

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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 and other information contained in this report.

### **Overview**

Antares Pharma, Inc. ( Antares, the Company, we or our ) is an emerging specialty pharmaceutical company that focuses on developing and commercializing self-administered parenteral pharmaceutical products and technologies. We have numerous partnerships with pharmaceutical companies as well as multiple internal product development programs. We have developed both subcutaneous and intramuscular injection technology systems which include Vibex® disposable pressure-assisted auto injectors, reusable needle-free injectors, and disposable multi-use pen injectors.

On October 14, 2013 we announced the approval of OTREXUP (methotrexate) injection by the FDA, and in January 2014 we announced the launch of OTREXUP and in February began detailing the product to health care professionals. OTREXUP is the first FDA approved subcutaneous methotrexate for once weekly self-administration with an easy-to-use, single dose, disposable auto injector. OTREXUP is indicated for adults with severe active rheumatoid arthritis ( RA ) or children with active polyarticular juvenile idiopathic arthritis and adults with severe recalcitrant psoriasis. We have worldwide marketing rights for OTREXUP and will commercialize OTREXUP on our own in the U.S. for the treatment of RA and we have provided LEO Pharma the exclusive right to commercialize OTREXUP in the U.S. for the treatment of psoriasis.

We are also developing Vibex® QS T for testosterone replacement therapy for men suffering from symptomatic testosterone deficiency. In February 2014 we announced positive top line results from a clinical study evaluating the PK 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 hypogonadal adult males. The study enrolled 39 patients at nine investigative sites in the United States. 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. We intend to begin a Phase 3 clinical study in 2014 to validate our results in a larger group of hypogonadal men over an extended period of at-home weekly dosing.

We have licensed our reusable needle-free injection device for use with human growth hormone ( hGH ) to Teva Pharmaceutical Industries, Ltd. ( Teva ), Ferring Pharmaceuticals BV ( Ferring ) and JCR Pharmaceuticals Co., Ltd. ( JCR ), with Teva and Ferring being two of our primary customers. Our needle-free injection device is marketed by Teva as the Tjet® injector system to administer their 5mg Tev-Tropin® brand hGH marketed in the U.S. Our needle-free injection device is marketed by Ferring with their 4mg and 10mg hGH formulations as Zomajet® 2 Vision and Zomajet® Vision X, respectively, in Europe and Asia. We have also licensed both disposable auto and pen injection devices to Teva for use in certain fields and territories and are engaged in product development activities for Teva utilizing these devices.

We also have a portfolio of gel-based products. Gelnique 3% , our topical oxybutynin gel product for the treatment of overactive bladder ( OAB ), which was approved by the FDA in December 2011, is currently being marketed by Actavis plc in the U.S. We also entered into a licensing agreement with Daewoong Pharmaceuticals under which Daewoong will commercialize this product, once approved in South Korea. Our gel portfolio also includes Elestrin® (estradiol gel) currently marketed by Meda Pharma in the U.S. for the treatment of moderate-to-severe vasomotor symptoms associated with menopause.

We have two facilities in the U.S. The Parenteral Products Group located in Minneapolis, Minnesota directs the manufacturing and marketing of our reusable needle-free injection devices and related disposables, and develops our disposable pressure-assisted auto injector and pen injector systems. Our corporate head office, Product Development Group and Commercial Group are located in Ewing, New Jersey, where the Product Development Group directs the clinical, regulatory and pre-commercial development of our internal drug/device combination products. Our Commercial Group is responsible for sales, marketing, medical affairs, trade, and third party reimbursement for our internally developed products.

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We have reported a net loss of \$8,794,605 for the three months ended March 31, 2014. Operating results for the three months ended March 31, 2014 are not necessarily indicative of the results that may be expected for the year ending December 31, 2014.

## **Results of Operations**

### *Three Months Ended March 31, 2014 and 2013*

#### *Revenues*

Total revenue for the three month period ended March 31, 2014 was \$5,202,195 compared to \$4,528,222 in the same period of the prior year.

#### *Product sales*

Product sales were \$1,805,302 and \$2,492,476 in the first quarters of 2014 and 2013, respectively.

In the first quarters of 2014 and 2013, sales of our reusable needle-free injector devices and disposable components were \$1.2 million and \$1.1 million, respectively, and were generated primarily from sales to Ferring and Teva. Ferring uses our needle-free injector with their 4mg and 10mg hGH formulations marketed as Zomajet<sup>®</sup> 2 Vision and Zomajet<sup>®</sup> Vision X, respectively, in Europe and Asia. Teva uses our needle-free injector with the Tjet<sup>®</sup> injector system to administer their 5mg Tev-Tropin<sup>®</sup> brand hGH marketed in the U.S. Sales of the hGH drug product for both Ferring and Teva continue to be strong, but we do not control our partners' inventory levels of our hGH injectors or disposable components and this can cause significant fluctuations in product sales.

During the quarter ended March 31, 2014, we began recognizing product revenues from sales of OTREXUP<sup>®</sup> made by us and by LEO Pharma under our license and promotion agreement. We began detailing OTREXUP<sup>®</sup> to rheumatologists in February 2014 and LEO Pharma began detailing to dermatologists in mid-March 2014. For the three months ended March 31, 2014 we recognized OTREXUP<sup>®</sup> net product sales of \$212,845 based on early prescription data.

We sell OTREXUP<sup>®</sup> in a package of four pre-filled, single-dose disposable auto injectors to wholesale pharmaceutical distributors, our customers, at a wholesale acquisition cost, or gross sales price, of \$548 per package as of March 31, 2014. Sales to our customers are subject to specified rights of return. We currently defer recognition of revenue on product shipments of OTREXUP<sup>®</sup> to our customers until the right of return no longer exists, which occurs at the earlier of the time OTREXUP<sup>®</sup> units are dispensed through patient prescriptions or expiration of the right of return.

We had a deferred revenue balance of \$2.1 million at March 31, 2014 for OTREXUP<sup>®</sup> product shipments to wholesalers, which is net of estimated wholesaler fees, stocking allowances, prompt pay discounts, rebates and patient discount programs. 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.

Product sales in the first quarter of 2014 also included \$336,000 of sales of pre-commercial pen injector devices to Teva. Product sales in the first quarter of 2013 included \$566,000 of initial sales to Teva of pre-launch quantities of our Vibex<sup>®</sup> auto injector for Teva's generic epinephrine auto injector product and \$510,000 of sales of our topical oxybutynin gel 3% product to Actavis in connection with their marketing of Gelnique 3%. Product sales to Actavis ended after the first quarter of 2013, as Actavis assumed all manufacturing of Gelnique 3% as contracted. In addition,

product revenue in the first quarter of 2013 included \$300,000 of revenue that had previously been deferred.

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### *Development revenue*

Development revenue was \$1,421,149 and \$793,710 in the first quarters of 2014 and 2013, respectively. The revenue in each period was primarily related to the Teva auto injector and pen injector programs.

### *Licensing revenue*

Licensing revenue was \$928,129 and \$69,345 in the first quarters of 2014 and 2013, respectively. The licensing revenue in the first quarter of 2014 was primarily due to revenue recognized in connection with payments received under our license and promotion agreement with LEO Pharma executed in November of 2013, which is being recognized over a 35 month period. The licensing revenue in the first quarter of 2013 was primarily due to recognition of revenue deferred in prior years under agreements with Ferring.

### *Royalty revenue*

Royalty revenue was \$1,047,615 and \$1,172,691 in the first quarters of 2014 and 2013, respectively. We receive royalties from Teva and Ferring related to needle-free injector device sales and/or hGH sales, from Meda Pharma on sales of Elestrin<sup>®</sup> and from Actavis on sales of Gelnique 3%. The slight decrease year over year was related to a decrease in the Gelnique royalty.

### *Cost of Revenues and Gross Profit*

The cost of product sales includes product acquisition costs from third party manufacturers, freight and indirect personnel and other overhead costs as well as reserves for excess, dated or obsolete commercial inventories and production manufacturing variances. For the three month periods ended March 31, 2014 and 2013, cost of product sales were \$1,017,437 and \$1,427,641, respectively. Product gross margins were 44% and 43% in three months ended March 31, 2014 and 2013, respectively.

The cost of development revenue consists primarily of direct external costs, some of which may have been previously incurred and deferred. Cost of development revenue was \$159,308 and \$599,502 for the first quarters of 2014 and 2013, respectively. In the first three months of each year, the development costs were primarily related to revenue recognized in connection with auto injector and pen injector development programs with Teva.

### *Research and Development*

The majority of research and development expenses consist of external costs for studies and analysis activities, design work and prototype development, and salaries and overhead costs. Research and development expenses were \$4,533,626 and \$3,072,685 in the three months ended March 31, 2014 and 2013, respectively. The increase in the first quarter of 2014 compared to the first quarter of the prior year was primarily due to an increase in expenses of approximately \$1.3 million related to development of our Vibex QS T for testosterone replacement therapy to \$1.9 million for the quarter. Additionally, personnel costs increased from approximately \$1.5 million to \$1.8 million due to employee additions during the last 12 months.

### *Sales and Marketing*

Sales and marketing expenses totaled \$5,510,202 and \$881,253 for the three months ended March 31, 2014 and 2013, respectively. Our sales and marketing expenses are related to marketing and promotion of OTREXUP and consist primarily of costs incurred with our third party contract sales organization, salaries and benefits of sales and marketing

personnel, marketing and advertising costs, sample product costs, and consulting fees. The significant increase in expenses in the first quarter of 2014 compared to 2013 was the direct result of the launch of OTREXUP in February 2014. Sales and marketing expenses in the first quarter of 2013 were primarily related to OTREXUP market research and pre-commercialization activities.



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**Table of Contents***General and Administrative*

General and administrative expenses totaled \$2,789,966 and \$1,950,430 in the three months ended March 31, 2014 and 2013, respectively. Our general and administrative expenses consist primarily of salaries and related costs for personnel in executive, finance, accounting, business development and internal support functions. In addition, general and administrative expenses include directors' compensation, facility costs and professional fees for legal, consulting and accounting services. The increase in the first quarter of 2014 compared to 2013 was due primarily to an increase in legal fees, professional fees and personnel costs. In addition, insurance expense was higher in the first quarter of 2014 partially as a result of a one time insurance refund received in the first quarter of 2013 which reduced expense in that period.

**Liquidity and Capital Resources**

At March 31, 2014, our cash and investments totaled \$63,064,813, which consisted of cash and cash equivalents of \$39,057,450, short-term investments of \$21,002,297, and long-term investments of \$3,005,066. 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, license revenues, milestone payments and royalties will provide us with sufficient funds to support operations. We do not currently have any bank credit lines.

*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. Net cash used in operating activities was \$6,960,888 and \$4,043,143 for the three months ended March 31, 2014 and 2013, respectively. The increase in cash used in operating activities in the first three months of 2014 compared to 2013 was primarily the result of an increase in the net loss for the quarter of \$5,386,157, which was significantly affected by the increase of \$4,628,949 in sales and marketing expenses in connection with the launch of OTREXUP. Additionally, in the first quarter of 2014 cash of \$2,084,112 was used to reduce accounts payable and accrued expenses. Partially offsetting these uses of cash was a \$5.0 million milestone payment received from LEO Pharma recorded as an increase to deferred revenue.

*Net Cash Provided by (Used in) Investing Activities*

Net cash provided by investing activities was \$5,829,040 in the first quarter of 2014, compared to the first quarter of 2013 which resulted in net cash used in investing activities of \$9,919,861. Cash used for purchases of equipment, molds, furniture and fixtures was \$128,701 in 2014 compared to \$763,600 in 2013, primarily related to OTREXUP commercial molds and assembly equipment. Additions to patent rights were \$42,259 in 2014 compared to \$38,100 in 2013. In the first three months of 2014 we received proceeds of \$6,000,000 from the maturity of investment securities and in 2013 we used cash of \$9,118,161 to purchase investment securities. The investment securities are U.S. Treasury bills or U.S. Treasury notes that are classified as held-to-maturity because we have the positive intent and ability to hold the securities to maturity.

*Net Cash Provided by (Used in) Financing Activities*

Net cash provided by financing activities was \$1,121,812 in the first three months of 2014 and net cash used in financing activities in the first three months of 2013 was \$1,260. In the first three months of 2014 we received proceeds of \$545,000 from the exercise of 545,000 warrants with an exercise price of \$1.00 and 570,178 options resulting in proceeds of \$691,935. In the first three months of 2013 we received \$52,823 from the exercise of 52,823 warrants with an exercise price of \$1.00 and 78,417 options resulting in proceeds of \$50,246. In the first three months of 2014 and 2013, total payments for employees' income and employment tax obligations related to net share settlement of equity awards was \$115,123 and \$104,329, respectively.

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**Research and Development Programs**

Our current research and development activities are primarily related to Vibex<sup>®</sup> QS T and device development projects.

**Vibex<sup>®</sup> QS T.** We are developing Vibe<sup>®</sup> QS T for self-administered weekly injections of testosterone enanthate in a preservative free formulation for clinically hypogonadal men requiring testosterone replacement. The Vibex<sup>®</sup> QS T injector is based on our Vibex<sup>®</sup> QS auto injector system which offers a dose capacity of 1 mL and greater in a compact design. Vibex<sup>®</sup> QS is designed to enhance performance on the attributes most critical to patient acceptance - speed, comfort and discretion. Vibex<sup>®</sup> QS achieves these advancements by incorporating a novel triggering mechanism and space-saving spring configuration. The design also accommodates fast injection of highly-viscous drug products, such as testosterone, that stall less-powerful conventional auto injectors.

In September 2013, we announced that the first patients were dosed in a clinical study evaluating the PK of testosterone enanthate administered weekly by subcutaneous injection at doses of 50 mg and 100 mg via the VIBEX<sup>®</sup> QS T auto injector device in hypogonadal adult males. The study enrolled 39 patients at nine investigative sites in the United States. We announced our top line results of this study on February 20, 2014. The results are considered positive in that Vibex<sup>®</sup> QS T treatment resulted in most patients achieving average levels of testosterone within the normal range from the first dose onward. Vibex<sup>®</sup> QS T was also safe and well tolerated by all dosed patients. We intend to begin Phase 3 clinical study in 2014 to validate our results in a larger group of hypogonadal men over an extended period of at-home weekly dosing.

In addition to collecting PK, efficacy and safety information, the phase 3 study will also collect Actual Human Use experience with the device from the hypogonadal male patients that will receive Vibex<sup>®</sup> QS T for home use. The study will assess the safe usability of Vibex<sup>®</sup> QS T for self-administration following standardized training by site personnel and review of written instructions. Additional assessments will include reliability, ease of use, robustness of Vibex<sup>®</sup> QS T, as well as an evaluation of the effectiveness of the patient education tools, including written instructions for use.

We have incurred external costs of approximately \$6,300,000 in connection with the Vibex<sup>®</sup> QS T program, of which approximately \$1,900,000 was recognized as expense in 2014. We anticipate total spending on this program for development and capital equipment could approach \$13,000,000 in 2014.

**Device Development Projects.** We are also engaged in research and development activities related to our Vibex<sup>®</sup> disposable pressure-assisted auto injectors and our disposable pen injectors. We have signed license agreements with Teva for our Vibex<sup>®</sup> system for use with epinephrine and sumatriptan and for our pen injector device for two undisclosed products. Our pressure-assisted auto injectors are designed to deliver drugs by injection from single-dose prefilled syringes. The auto injectors are in the advanced commercial stage of development. The disposable pen injector device is designed to deliver drugs by injection through needles from multi-dose cartridges. The disposable pen is in the stage of development where devices are being evaluated in user studies and stability programs. Our development programs consist of the determination of the device design, development of prototype tooling, production of prototype devices for testing and clinical studies, performance of clinical studies, and development of commercial tooling and assembly.

As of March 31, 2014, excluding costs related to OTREXUP<sup>®</sup> and Vibe<sup>®</sup> QS T, we have incurred total external costs of approximately \$15,300,000 in connection with research and development activities associated with our auto and pen injectors, both with partners and on our own, of which approximately \$600,000 was incurred in 2014. Costs incurred in connection with development programs with partners are generally initially deferred and are recognized as cost of development revenue when revenue is recognized. Approximately \$12,000,000 of the total costs of

\$15,300,000 was initially deferred, of which approximately \$14,800,000 has been recognized as cost of development revenue and \$500,000 remains deferred as of March 31, 2014. This remaining deferred balance will be recognized as cost of development revenue over the same period as the related deferred revenue will be recognized.

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The development timelines of the auto and pen injectors related to the Teva products are controlled by Teva. We expect development related to the Teva products to continue in 2014, but the timing and extent of near-term future development will be dependent on certain decisions made by Teva. Although development work payments and certain upfront and milestone payments have been received from Teva, there have been no commercial sales from the auto injector or pen injector programs, timelines have been extended and there can be no assurance that there ever will be commercial sales or future milestone payments under these agreements.

**Other research and development costs.** In addition to the Vibex<sup>®</sup> QS T project and the Teva 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 salaries, administrative and other overhead costs of managing our research and development projects. Total other research and development costs were approximately \$2,600,000 for the three months ended March 31, 2014.

## **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 and valuation of long-lived and intangible assets and goodwill, as 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, 2013.

## ***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 period ended March 31, 2014 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, 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

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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 are 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.

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**PART II - OTHER INFORMATION**

*Item 1. LEGAL PROCEEDINGS*

In the first quarter of 2014 Medac Pharma announced that it submitted an NDA to the FDA for an auto-pen containing methotrexate. On February 28, 2014, Antares filed a complaint against Medac Pharma and Medac GmbH ( Medac GmbH , together with Medac Pharma, Medac ), the parent company of Medac Pharma, in the United States District Court for the District of Delaware, alleging infringement of two of the Company s patents for technology regarding an auto-injector and an auto-injector containing methotrexate. The complaint asserts that Medac Pharma s NDA submission infringes, that Medac Pharma s proposed product will infringe the Company s patents, and that Medac Pharma should be enjoined from marketing its product.

On March 7, 2014, Medac filed suit against Antares, LEO Pharma and its parent company LEO Pharma A/S (together, the LEO Entities ) in the United States District Court for the District of New Jersey, alleging that Antares and the LEO Entities infringe Medac s U.S. Patent 8,664,231 (the 231 patent ) that was issued by the U.S. Patent and Trademark Office on March 4, 2014. The complaint states that the 231 patent relates to a concentration of more than 30mg/mL. Medac alleges that OTREXUP infringes the 231 patent, and demands that Antares and the LEO Entities be enjoined from making, using, selling, importing or offering OTREXUP and pay unspecified amounts of compensatory damages, treble damages and attorneys fees. The Company intends to defend itself vigorously. Under the terms of the promotion and license agreement between the Company and the LEO Entities, the Company agreed to indemnify the LEO Entities from claims that OTREXUP infringes the intellectual property rights of any third party.

*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, 2013, which could materially affect our business, financial condition or future results. 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.



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## (a) Exhibit Index

Exhibit No.	Description
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.

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**SIGNATURES**

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

**ANTARES PHARMA, INC.**

May 9, 2014

/s/ Paul K. Wotton  
Dr. Paul K. Wotton  
President and Chief Executive Officer

May 9, 2014

/s/ Robert F. Apple  
Robert F. Apple  
Executive Vice President and Chief Financial Officer