

ANTARES PHARMA, INC.  
Form 10-Q  
November 06, 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 September 30, 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 November 1, 2014 was 131,684,193.

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

	<b>September 30, 2014 (Unaudited)</b>	<b>December 31, 2013</b>
<b>Assets</b>		
Current Assets:		
Cash and cash equivalents	\$ 39,050,832	\$ 39,067,236
Short-term investments	9,003,215	24,014,305
Accounts receivable	2,272,373	1,034,492
Inventories	7,992,961	6,461,051
Deferred costs	1,689,497	375,773
Prepaid expenses and other current assets	929,141	1,706,678
<b>Total current assets</b>	<b>60,938,019</b>	<b>72,659,535</b>
Equipment, molds, furniture and fixtures, net	9,668,417	6,952,251
Patent rights, net	2,960,864	1,345,177
Goodwill	1,095,355	1,095,355
Long-term investments		6,008,169
Other assets	871,168	871,444
<b>Total Assets</b>	<b>\$ 75,533,823</b>	<b>\$ 88,931,931</b>
<b>Liabilities and Stockholders Equity</b>		
Current Liabilities:		
Accounts payable	\$ 8,030,911	\$ 6,378,712
Accrued expenses and other liabilities	5,980,708	5,453,075
Deferred revenue	6,891,503	4,531,220
<b>Total current liabilities</b>	<b>20,903,122</b>	<b>16,363,007</b>
Deferred revenue long term	4,225,568	1,855,196
<b>Total liabilities</b>	<b>25,128,690</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; 131,592,798 and 128,740,604 issued and outstanding at September 30, 2014 and December 31, 2013, respectively	1,315,928	1,287,406
Additional paid-in capital	248,149,323	243,375,465

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Accumulated deficit	(198,374,712)	(173,295,941)
Accumulated other comprehensive loss	(685,406)	(653,202)
	50,405,133	70,713,728
<b>Total Liabilities and Stockholders Equity</b>	<b>\$ 75,533,823</b>	<b>\$ 88,931,931</b>

See accompanying notes to consolidated financial statements.

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

	<b>For the Three Months Ended September 30,</b>		<b>For the Nine Months Ended September 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
<b>Revenue:</b>				
Product sales	\$ 3,559,579	\$ 3,047,091	\$ 8,724,884	\$ 10,052,458
Development revenue	1,744,735	1,299,328	4,954,285	2,681,202
Licensing revenue	926,955	69,231	2,783,434	207,238
Royalties	339,312	1,092,174	1,636,958	2,932,692
<b>Total revenue</b>	<b>6,570,581</b>	<b>5,507,824</b>	<b>18,099,561</b>	<b>15,873,590</b>
<b>Cost of revenue:</b>				
Cost of product sales	2,158,266	1,909,060	5,021,896	6,519,468
Cost of development revenue	349,100	1,095,542	792,295	1,992,959
<b>Total cost of revenue</b>	<b>2,507,366</b>	<b>3,004,602</b>	<b>5,814,191</b>	<b>8,512,427</b>
<b>Gross profit</b>	<b>4,063,215</b>	<b>2,503,222</b>	<b>12,285,370</b>	<b>7,361,163</b>
<b>Operating expenses:</b>				
Research and development	4,426,730	4,318,011	12,903,304	11,786,224
Sales and marketing	4,242,775	2,576,247	14,766,906	4,615,736
General and administrative	2,567,314	1,978,144	9,688,261	5,862,342
<b>Total operating expenses</b>	<b>11,236,819</b>	<b>8,872,402</b>	<b>37,358,471</b>	<b>22,264,302</b>
<b>Operating loss</b>	<b>(7,173,604)</b>	<b>(6,369,180)</b>	<b>(25,073,101)</b>	<b>(14,903,139)</b>
Other income (expense)	(12,837)	9,223	(5,670)	31,478
<b>Net loss</b>	<b>\$ (7,186,441)</b>	<b>\$ (6,359,957)</b>	<b>\$ (25,078,771)</b>	<b>\$ (14,871,661)</b>
<b>Basic and diluted net loss per common share</b>	<b>\$ (0.05)</b>	<b>\$ (0.05)</b>	<b>\$ (0.19)</b>	<b>\$ (0.12)</b>
<b>Basic and diluted weighted average common shares outstanding</b>	<b>130,771,380</b>	<b>127,162,064</b>	<b>130,163,929</b>	<b>126,581,018</b>

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 September 30,</b>		<b>For the Nine Months Ended September 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
Net loss	\$ (7,186,441)	\$ (6,359,957)	\$ (25,078,771)	\$ (14,871,661)
Foreign currency translation adjustment	(32,114)	21,611	(32,204)	3,167
Comprehensive loss	\$ (7,218,555)	\$ (6,338,346)	\$ (25,110,975)	\$ (14,868,494)

See accompanying notes to consolidated financial statements.

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

	<b>For the Nine Months Ended September 30,</b>	
	<b>2014</b>	<b>2013</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (25,078,771)	\$ (14,871,661)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation and amortization	873,158	288,188
Stock-based compensation expense	1,898,241	1,534,100
Amortization of premiums and discounts	19,259	174,308
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable	(1,237,907)	(1,176,745)
Inventories	(1,531,910)	(804,009)
Prepaid expenses and other current assets	776,389	(524,141)
Deferred costs	(1,313,724)	440,051
Other assets	276	(11,844)
Accounts payable	(220,962)	1,387,543
Accrued expenses and other current liabilities	605,211	1,946,548
Deferred revenue	4,733,129	(1,676,365)
<b>Net cash used in operating activities</b>	<b>(20,477,611)</b>	<b>(13,294,027)</b>
<b>Cash flows from investing activities:</b>		
Purchases of equipment, molds, furniture and fixtures	(2,829,738)	(2,184,568)
Additions to patent rights	(461,943)	(195,558)
Proceeds from maturities of investment securities	21,000,000	15,000,000
Purchases of investment securities	(9,118,161)	(9,118,161)
<b>Net cash provided by investing activities</b>	<b>17,708,319</b>	<b>3,501,713</b>
<b>Cash flows from financing activities:</b>		
Proceeds from exercise of stock options and warrants	2,908,540	756,611
Taxes paid related to net share settlement of equity awards	(154,397)	(104,329)
<b>Net cash provided by financing activities</b>	<b>2,754,143</b>	<b>652,282</b>
<b>Effect of exchange rate changes on cash and cash equivalents</b>	<b>(1,255)</b>	<b>3,454</b>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>(16,404)</b>	<b>(9,136,578)</b>
<b>Cash and cash equivalents:</b>		
Beginning of period	39,067,236	52,097,064



End of period	\$ 39,050,832	\$ 42,960,486
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Noncash investing activities:

Purchases of equipment, molds, furniture and fixtures recorded in accounts payable and accrued expenses	\$ 526,137	\$ 437,504
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Additions to patent rights recorded in accounts payable and accrued expenses	1,423,227	
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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<sup>®</sup> 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 U.S. Food and Drug Administration (FDA), 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 commercializes OTREXUP in the U.S. for the treatment of RA and has provided LEO Pharma Inc. (LEO) the exclusive right to commercialize OTREXUP in the U.S. for the treatment of psoriasis.

The Company is also developing Vibex<sup>®</sup> QuickShot<sup>®</sup> Testosterone (QST) 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 pharmacokinetics of testosterone enanthate administered weekly by subcutaneous injection at doses of 50 mg and 100 mg via the Vibex<sup>®</sup> QST auto injector device in adult males with testosterone deficiency. The study results were considered positive in that most of the 39 patients enrolled achieved average levels of testosterone within the normal range from the first dose onward. Vibex<sup>®</sup> QST was also safe and well tolerated by all dosed patients. On July 22, 2014, the Company announced that the first patient was dosed in a Phase 3 double-blind, multiple-dose study to evaluate the efficacy and safety of Vibex<sup>®</sup> QST administered subcutaneously once each week to adult males with testosterone deficiency. In October 2014, the Company announced the last patient was enrolled in the study. It is anticipated that patients will continue to be dosed in the study until the second half of 2015.

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<sup>®</sup> injector system to administer their 5mg Tev-Tropin<sup>®</sup> 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<sup>®</sup> 2 Vision and Zomajet<sup>®</sup> 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%<sup>®</sup>, the Company's topical oxybutynin gel product for the treatment of overactive bladder (OAB), is currently being marketed by Actavis plc (Actavis) in the

U.S. The Company's gel portfolio also includes Elestrin® (estradiol gel) currently marketed by Meda Pharmaceuticals Inc. in the U.S. for the treatment of moderate-to-severe vasomotor symptoms associated with menopause.

**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 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 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 and nine months ended September 30, 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. Business development expenses previously reported separately 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. At September 30, 2014, the short-term investments had a fair value of \$9,009,756 and a carrying value of \$9,003,215. 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. The Company provides reserves for potentially excess, dated or obsolete inventories based on an analysis of inventory on hand compared to forecasts of future sales. Inventories consist of the following:

	<b>September 30, 2014</b>	<b>December 31, 2013</b>
Inventories:		
Raw material	\$ 781,002	\$ 1,056,054
Work in process	5,262,008	3,034,321
Finished goods	1,949,951	2,370,676
	<b>\$ 7,992,961</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 September 30, 2014 and December 31, 2013, \$1.8 million and \$0.1 million, respectively, of external legal patent costs were capitalized within patent rights, net.

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In February 2014, the Company began detailing OTREXUP<sup>®</sup> 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<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 \$4,491,288 in OTREXUP<sup>®</sup> product revenue from U.S. customers for the nine months ended September 30, 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 \$1,002,445 at September 30, 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 September 30, 2014, the Company has been subject to a minimal amount of chargebacks. 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. 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 will estimate and accrue 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.

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*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**

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 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 10 years and the options typically vest in quarterly installments over a three-year period. As of September 30, 2014, the Plan had 4,386,709 shares available for grant. Stock option exercises are satisfied through the issuance of new shares.

*Stock Options*

A summary of stock option activity under the Plan as of September 30, 2014, and the changes during the nine months then ended is as follows:

	Number of Shares	Weighted Average Exercise Price (\$)	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (\$)
Outstanding at December 31, 2013	7,697,892	1.89		
Granted	1,957,701	3.08		
Exercised	(1,991,728)	1.19		3,499,052
Cancelled/Forfeited	(556,675)	3.36		



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Outstanding at September 30, 2014	7,107,190	2.30	6.3	2,050,397
Exercisable at September 30, 2014	4,893,821	1.85	5.0	2,050,397

Total recognized compensation expense for stock options was approximately \$1,451,000 and \$982,000 for the first nine months of 2014 and 2013, respectively and was approximately \$643,000 and \$401,000 for the three month periods ended September 30, 2014 and 2013, respectively. As of September 30, 2014, there was approximately \$3,500,000 of total unrecognized compensation cost related to nonvested outstanding stock options that is expected to be recognized over a weighted average period of approximately 2.0 years.

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The per share weighted average fair values of options granted during the first nine months of 2014 and 2013 were estimated as \$3.08 and \$2.27 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.

	<b>September 30,</b>	
	<b>2014</b>	<b>2013</b>
Risk-free interest rate	1.7%	0.7%
Annualized volatility	62.0%	62.5%
Weighted average expected life, in years	6.0	6.0
Expected dividend yield	0.0%	0.0%

In the first nine months of 2014, 1,991,728 stock options with a weighted average exercise price of \$1.19 were exercised which generated proceeds of \$2,363,425 to the Company. In the first nine months of 2013, 707,285 stock options with a weighted average exercise price of \$0.72 were exercised which generated proceeds of \$508,638 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 or in the second or third quarters of 2014.

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 \$356,000 and \$470,000 in the nine month period ended September 30, 2014 and 2013, respectively and was \$13,000 and \$204,000 in the three month periods ended September 30, 2014 and 2013, respectively.

*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 and performance stock units with targeted values based on values granted by the Company's peer group. In 2014, the program was modified such that the value of the annual award for each senior executive was delivered 50% in the form of performance stock units, 25% in the form of shares of restricted stock and 25% in the form of stock options. In the prior year, 33% of the value for each senior executive was delivered in the form of stock options, 33% of the value was delivered in the form of performance stock units and 33% was delivered in the form of restricted stock. 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 nine months of 2014 in connection with the restricted stock was approximately \$150,000. 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. In connection with performance stock unit awards for defined performance goals considered probable of achievement, a net expense reduction of \$55,000 was recognized

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in the first nine months of 2014. The net expense reduction was primarily the result of the reversal of expense associated with awards previously granted to senior executives who left the Company in 2014 where the awards will not vest. The performance stock unit awards and restricted stock granted under the long term incentive program are summarized in the following table:

	Performance Stock Units		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	651,980	3.02	325,991	3.02
Vested	(75,000)	1.66	(51,907)	3.96
Forfeited/Expired	(400,360)	3.21	(150,726)	3.45
Outstanding at September 30, 2014	583,283	3.19	279,082	3.14

A portion of the shares that were granted as discretionary shares or under the LTIP that vested in the first nine months 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 38,768 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 \$154,397 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 nine months of 2014, the Company received proceeds of \$545,115 from the exercise of 545,100 warrants. In the first nine months of 2013, the Company received proceeds of \$261,799 from the exercise of 234,541 warrants. There were 545,100 warrants outstanding at December 31, 2013 and none outstanding at September 30, 2014.

**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 7,107,190 and 9,595,808 at September 30, 2014 and 2013, respectively. The table below discloses the basic and diluted loss per common share.

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
Net loss	\$ (7,186,441)	\$ (6,359,957)	\$ (25,078,771)	\$ (14,871,661)
Basic and diluted wtd avg common shares outstanding	130,771,380	127,162,064	130,163,929	126,581,018
Basic and diluted net loss per common share	\$ (0.05)	\$ (0.05)	\$ (0.19)	\$ (0.12)

**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 September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
United States of America	\$ 5,823,339	\$ 4,390,966	\$ 14,310,806	\$ 13,063,929
Europe	735,613	1,047,748	3,565,616	2,585,655
Other	11,629	69,110	223,139	224,006
	\$ 6,570,581	\$ 5,507,824	\$ 18,099,561	\$ 15,873,590

Revenues by product type:

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
Injection devices and supplies	\$ 6,227,784	\$ 5,100,253	\$ 17,152,778	\$ 13,882,973
Transdermal products	342,797	407,571	946,783	1,990,617
	\$ 6,570,581	\$ 5,507,824	\$ 18,099,561	\$ 15,873,590

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

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
Teva	\$ 1,779,595	\$ 4,004,531	\$ 6,084,408	\$ 11,196,559
Ferring	734,013	1,047,750	3,564,021	2,511,332
LEO Pharma	857,143		2,571,429	
Actavis	145,332	202,813	326,079	1,301,929

**6. License Agreements***Development and License Agreement*

In September 2014 the Company entered into a development and license agreement with an undisclosed pharmaceutical partner, under which the Company will develop and supply an auto injector product for delivery of an undisclosed drug. Under the agreement, an upfront payment, development milestones, and royalties on the partner's

product sales, as well as a purchase price for each device sold are to be received by the Company. The Company identified and evaluated a number of deliverables in the agreement and concluded that the manufacturing deliverable has stand-alone value but the license and development work do not have value on a stand-alone basis. As a result, the license and development deliverables do not qualify for treatment as separate units of accounting. Accordingly, the deliverables will be accounted for as a single unit of accounting and will be recognized as revenue during the estimated development period. The Company recognized revenue in the three and nine month periods ended September 30, 2014 of approximately \$240,000 and recorded deferred revenue of \$435,000 at September 30, 2014 in connection with this agreement.

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**Table of Contents***LEO Pharma Promotion and License Agreement*

In November 2013 the Company entered into a promotion and license agreement with LEO. Under this agreement, the Company granted LEO the exclusive right to promote OTREXUP<sup>®</sup> 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<sup>®</sup> 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 in the three and nine month periods ended September 30, 2014 of approximately \$857,000 and \$2,571,000, respectively, and recorded deferred revenue of \$6,857,000 at September 30, 2014 in connection with this agreement.

**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, Inc. (Medac Pharma) announced that it submitted a New Drug Application (NDA) to the FDA for an auto-pen containing methotrexate. On February 28, 2014, Antares filed a complaint against Medac Pharma and Medac GmbH, the parent company of Medac Pharma, (Medac GmbH, together with Medac Pharma, Medac) 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 14, 2014, Antares filed a motion for preliminary injunction seeking to enjoin Medac from selling its methotrexate auto-pen product if and when such product is approved for sale in the United States, pending the final resolution of the litigation. On April 18, an amended complaint was filed asserting four Antares patents, and the motion for preliminary injunction was updated. On July 10, 2014, the District Court denied Antares' motion for preliminary injunction. The



litigation is expected to proceed to a jury trial unless settled by the parties; a trial date has not been set. Antares has filed an appeal of the denial of the motion for preliminary injunction with the U.S. Court of Appeals for the Federal Circuit. During the nine months ended September 30, 2014, a total of approximately \$1,700,000 in legal costs in connection with this suit has 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<sup>®</sup> 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.

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On March 7, 2014, Medac filed suit against Antares, LEO Pharma and its parent company, LEO Pharma A/S (LEO Pharma together with LEO Pharma A/S, the LEO Entities ) in the United States District Court for the District of New Jersey, alleging that Antares and the LEO Entities infringe Medac Pharma'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. On July 1, 2014, Antares filed a petition with the Patent Trial and Appeal Board (the PTAB ) of the U.S. Patent and Trademark Office seeking an inter partes review of the 231 patent. The PTAB must decide whether to institute review by January 2, 2015. Legal costs in connection with this suit and the inter partes review 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**

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 a 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);

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 ability to defend our intellectual property rights and the outcome of our pending litigation;

the impact of new accounting pronouncements and our expectations and estimates with regard to current accounting practices; and

our expectations regarding the year ending December 31, 2014.

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;

the outcome of our ongoing litigation matters;

our inability to attract and retain key personnel;

regulatory changes or delays in the regulatory process;

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 U.S. Food and Drug Administration ( FDA ), 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. We have worldwide marketing rights for OTREXUP and commercialize OTREXUP on our own in the U.S. for the treatment of RA, and we have provided LEO Pharma Inc. ( LEO Pharma ) the exclusive right to commercialize OTREXUP in the U.S. for the treatment of psoriasis.

We are also developing Vibex® QuickShot® Testosterone ( 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 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 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. On July 22, 2014, we announced that the first patient was dosed in a Phase 3, double-blind, multiple-dose study to evaluate the efficacy and safety of Vibex® QS T administered subcutaneously once each week to adult males with testosterone deficiency. In October 2014, we announced the last patient was enrolled in the study. It is anticipated that patients will continue to be dosed in the study until the second half of 2015.

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 ), is currently being marketed by Actavis plc ( Actavis ) in the U.S. Our gel portfolio also includes Elestrin® (estradiol gel) currently marketed by Meda Pharmaceuticals Inc. ( Meda Pharma ) in the U.S. for the treatment of moderate-to-severe vasomotor symptoms associated with menopause.



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We have reported a net loss of \$25,078,771 for the nine months ended September 30, 2014. Operating results for the nine months ended September 30, 2014 are not necessarily indicative of the results that may be expected for the year ending December 31, 2014.

## **Results of Operations**

### *Three and Nine Months Ended September 30, 2014 and 2013*

#### *Revenues*

Total revenue for the three and nine-month periods ended September 30, 2014 were \$6,570,581 and \$18,099,561 compared to \$5,507,824 and \$15,873,590 in the same prior-year periods, respectively.

#### *Product sales*

Product sales were \$3,559,579 and \$8,724,884 in the three and nine-month periods ended September 30, 2014, respectively, compared to \$3,047,091 and \$10,052,458 in the three and nine-month periods ended September 30, 2013, respectively.

Sales of our reusable needle-free injector devices and disposable components, generated primarily from sales to Ferring and Teva, were \$654,000 and \$3,599,000 in the three and nine-month periods ended September 30, 2014, respectively, and were \$969,000 and \$2,768,000 in the three and nine-month periods ended September 30, 2013, respectively. 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. Teva initiated a recall of the drug product, Tev-Tropin<sup>®</sup> (not the device which we supply), at the end of April and had halted sales of the drug earlier in the year. We do not know when Teva will resume sales of Tev-Tropin<sup>®</sup>. The recall has had a negative effect on the level of product sales to Teva. We do not control our partners' inventory levels of our hGH injectors or disposable components and this can cause significant fluctuations in product sales.

In the first half of 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 and nine-month periods ended September 30, 2014 we recognized OTREXUP<sup>®</sup> net product sales of \$2,607,000 and \$4,491,000, respectively, based on 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 September 30, 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 \$1,002,000 at September 30, 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 nine months of 2014 and 2013 also included \$635,000 and \$273,000, respectively, of sales of pre-commercial pen injector devices to Teva. Product sales in the third quarter and first nine months of 2013 included \$2,078,000 and \$6,204,000, respectively, of initial sales to Teva of our Vibex<sup>®</sup> auto injector for Teva's generic epinephrine auto injector product. We anticipate shipping additional auto injectors to Teva for their generic epinephrine product in the later part of 2014. Product sales in the first nine months of 2013 also included \$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 half of 2013 included \$300,000 of revenue that had previously been deferred.



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**Table of Contents***Development revenue*

Development revenue was \$1,744,735 and \$4,954,285 in the three and nine-month periods ended September 30, 2014, respectively, compared to \$1,299,328 and \$2,681,202 in the same periods of the prior year. The revenue in each period was primarily related to the Teva auto injector and pen injector programs.

*Licensing revenue*

Licensing revenue was \$926,955 and \$2,783,434 in the three and nine-month periods ended September 30, 2014, respectively, compared to \$69,231 and \$207,238 in the same periods of the prior year. The licensing revenue in 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 2013 was primarily due to recognition of revenue deferred in prior years under agreements with Ferring.

*Royalty revenue*

Royalty revenue was \$339,312 and \$1,636,958 in the three and nine-month periods ended September 30, 2014, respectively, compared to \$1,092,174 and \$2,932,692 in the same periods of the prior year. 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® and from Actavis on sales of Gelnique 3%. The decrease year over year was primarily the result of receiving no royalties from Teva in the second and third quarters of 2014. Our royalties from Teva are based on Teva's sales of their hGH drug, Tev-Tropin®. Teva initiated a recall of the drug product, Tev-Tropin® (not the device which we supply), at the end of April and had halted sales of the drug earlier in the year. We do not know when Teva will resume sales of Tev-Tropin®.

*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 and nine-month periods ended September 30, 2014, cost of product sales was \$2,158,266 and \$5,021,896, respectively, compared to \$1,909,060 and \$6,519,468 for the same periods of the prior year. Product gross margins were 39% and 37% in three-month periods ended September 30, 2014 and 2013, respectively, and were 42% and 35% for the nine-month periods ended September 30, 2014 and 2013, respectively. The gross margin increase in 2014 compared to 2013 was primarily the result of a change in the mix of products sold. The product revenue in 2013 consisted primarily of sales to Teva of our Vibex® auto injectors for epinephrine, which generated a lower gross margin than our needle-free and OTREXUP® products sold in 2014. The product gross margins for the three and nine month periods ended September 30, 2014 were reduced as a result of increases to the reserve for potential excess, dated or obsolete inventories in those periods of \$1,100,000 and \$1,350,000, 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 \$349,100 and \$792,295 for the three and nine-month periods ended September 30, 2014, respectively, compared to \$1,095,542 and \$1,992,959 for the same prior-year periods. 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 \$4,426,730 and \$12,903,304 in the three and nine-month periods ended September 30, 2014, respectively, compared to \$4,318,011 and \$11,786,224 in the same periods of the prior year. The fluctuations in expenses in each period are primarily related to the timing of spending on OTREXUP<sup>®</sup> development and development of our Vibe<sup>®</sup> QS T for testosterone replacement therapy.

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**Table of Contents***Sales and Marketing*

Sales and marketing expenses totaled \$4,242,775 and \$14,766,906 for the three and nine-month periods ended September 30, 2014, respectively, compared to \$2,576,247 and \$4,615,736 in the same prior-year periods. 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 third quarter and first nine months of 2014 compared to 2013 was the direct result of the launch of OTREXUP in February 2014. Sales and marketing expenses in the third quarter and first nine months of 2013 were primarily related to OTREXUP market research and pre-commercialization activities.

*General and Administrative*

General and administrative expenses totaled \$2,567,314 and \$9,688,261 in the three and nine-month periods ended September 30, 2014, respectively, compared to \$1,978,144 and \$5,862,342 in the same periods of the prior year. 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 third quarter and first nine months of 2014 compared to 2013 was due primarily to an increase in legal fees associated with the Medac litigation discussed in Note 8 to the consolidated financial statements, as well as an increase in professional fees.

**Liquidity and Capital Resources**

At September 30, 2014, our cash and investments totaled \$48,054,047, which consisted of cash and cash equivalents of \$39,050,832 and short-term investments of \$9,003,215. 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 \$20,477,611 and \$13,294,027 for the nine months ended September 30, 2014 and 2013, respectively. The increase in cash used in operating activities in the first nine months of 2014 compared to 2013 was primarily the result of an increase in the net loss for the year of \$10,207,110 to \$25,078,771, which was significantly affected by the increase of \$10,151,170 in sales and marketing expenses in connection with the launch of OTREXUP. Additionally, in the first nine months of 2014 cash of \$1,531,910 was used to build inventories, deferred costs increased by \$1,313,724 in connection with development projects with partners, and accounts receivable increased by \$1,237,907. Partially offsetting these uses of cash was an increase in deferred revenue of \$4,733,129.

*Net Cash Provided by Investing Activities*

Net cash provided by investing activities in the first nine months of 2014 and 2013 was \$17,708,319 and \$3,501,713, respectively. Cash used for purchases of equipment, molds, furniture and fixtures was \$2,829,738 in 2014 compared to \$2,184,568 in 2013, primarily related to OTREXUP commercial molds and assembly equipment. Additions to patent rights were \$461,943 in 2014 compared to \$195,558 in 2013. In the first nine months of 2014 and 2013 we received proceeds of \$21,000,000 and \$15,000,000, respectively, 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.

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### *Net Cash Provided by Financing Activities*

Net cash provided by financing activities in the first nine months of 2014 and 2013 was \$2,754,143 and \$652,282, respectively. In the first nine months of 2014 we received proceeds of \$545,115 and \$2,363,425 from the exercise of 545,100 warrants and 1,991,728 options, respectively. In the first nine months of 2013 we received proceeds of \$261,799 and \$494,812 from the exercise of 234,541 warrants and 707,285 options, respectively. In the first nine months of 2014 and 2013, total payments for employees' income and employment tax obligations related to net share settlement of equity awards was \$154,397 and \$104,329, respectively.

### **Research and Development Programs**

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

**Vibex® QS T.** We are developing Vibex® QS T for self-administered weekly injections of testosterone enanthate in a preservative free formulation for men requiring testosterone replacement. The Vibex® QS T injector is based on our Vibex® QS auto injector system which offers a dose capacity of 1 mL and greater in a compact design. Vibex® QS is designed to enhance performance on the attributes most critical to patient acceptance—speed, comfort and discretion. Vibex® 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 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 July 22, 2014, we announced that the first patient was dosed in a Phase 3, double-blind, multiple-dose study to evaluate the efficacy and safety of testosterone administered subcutaneously with the Vibex® QS T auto injector once each week to adult males with testosterone deficiency, defined as having testosterone levels below 300 ng/dL. In October 2014, we announced the last patient was enrolled in the study. In addition to collecting pharmacokinetic, efficacy and safety information, the phase 3 study will also collect Actual Human Use experience with the device from the male patients that will receive Vibex® QS T for home use. The study will assess the safe usability of Vibex® 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® QS T, as well as an evaluation of the effectiveness of the patient education tools, including written instructions for use. Approximately 150 patients will be enrolled in this study. Patients meeting all eligibility criteria will be assigned to receive a starting dose of Vibex® QS T once weekly for six weeks. Adjustments to dose may 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 will be evaluated after 12 weeks of treatment. Upon completion of this phase, patients may remain on their optimized Vibex® QS T dose and will be followed for an additional 40 weeks. Approximately 100 patients will be needed to complete collection of 26 weeks of safety data, and approximately 50 patients will be needed to complete collection of 52 weeks of safety data.

We have incurred external costs of approximately \$13,000,000 in connection with the Vibex® QS T program, of which approximately \$6,600,000 was recognized as expense in 2014 and \$2,000,000 was for capital equipment. We

anticipate total spending on this program for development and capital equipment of approximately \$11,000,000 in 2014.

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**Device Development Projects.** We are also engaged in research and development activities related to our Vibex® disposable pressure-assisted auto injectors and our disposable pen injectors. We have signed license agreements with Teva for our Vibex® system for 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 September 30, 2014, excluding costs related to OTREXUP and Vibe® QS T, we have incurred total external costs of approximately \$17,700,000 in connection with research and development activities associated with our auto and pen injectors, both with partners and on our own, of which approximately \$2,900,000 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 \$14,100,000 of the total costs of \$17,700,000 was initially deferred, of which approximately \$12,400,000 has been recognized as cost of development revenue and \$1,700,000 remains deferred as of September 30, 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.

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® 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 \$6,300,000 for the nine months ended September 30, 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.

## **Recently Issued Accounting Pronouncements**

In June 2014, the Financial Accounting Standards Board ( FASB ) issued ASU 2014-12, *Compensation – Stock Compensation: Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could be Achieved after the Requisite Service Period*, which provides explicit guidance for the accounting treatment for these types of awards. The ASU requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. As such, the performance target should not be reflected in estimating the grant-date fair value of the award. This update is effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. Early adoption is permitted. The Company does not expect the adoption of this ASU will have a material impact on its consolidated financial statements.



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On May 28, 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers*, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The ASU will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The new standard is effective for the Company on January 1, 2017. Early application is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. The Company is evaluating the effect that ASU 2014-09 will have on its consolidated financial statements and related disclosures. The Company has not yet selected a transition method nor has it determined the effect of the standard on its ongoing financial reporting.

### *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 September 30, 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 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.

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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 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. There have been no material changes to these risk factors. The risks described in our Annual Report on Form 10-K are not the only risks facing us. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

*Item 6. EXHIBITS*

## (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.**

November 6, 2014

/s/ Eamonn Hobbs  
Eamonn Hobbs  
President and Chief Executive Officer

November 6, 2014

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