

ANTARES PHARMA, INC.
Form 10-Q
May 11, 2015
Table of Contents

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, 2015

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, 2015 was 131,751,104.

Table of Contents

ANTARES PHARMA, INC.

INDEX

	PAGE
PART I.	
	<u>FINANCIAL INFORMATION</u>
Item 1.	<u>Financial Statements</u>
	<u>Consolidated Balance Sheets, as of March 31, 2015 (Unaudited) and December 31, 2014</u>
	3
	<u>Consolidated Statements of Operations (Unaudited) for the three months ended March 31, 2015 and 2014</u>
	4
	<u>Consolidated Statements of Comprehensive Loss (Unaudited) for the three months ended March 31, 2015 and 2014</u>
	5
	<u>Consolidated Statements of Cash Flows (Unaudited) for the three months ended March 31, 2015 and 2014</u>
	6
	<u>Notes to Condensed Consolidated Financial Statements (Unaudited)</u>
	7
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>
	16
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>
	24
Item 4.	<u>Controls and Procedures</u>
	24
PART II.	
	<u>OTHER INFORMATION</u>
Item 1A.	<u>Risk Factors</u>
	25
Item 6.	<u>Exhibits</u>
	25
	<u>SIGNATURES</u>
	26

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

	March 31, 2015 (Unaudited)	December 31, 2014
Assets		
Current Assets:		
Cash and cash equivalents	\$ 23,543,024	\$ 34,028,889
Short-term investments	3,001,024	6,002,438
Accounts receivable	4,208,270	3,510,051
Inventories	5,896,998	5,859,924
Deferred costs	1,708,664	1,913,921
Prepaid expenses and other current assets	3,006,784	2,322,464
Total current assets	41,364,764	53,637,687
Equipment, molds, furniture and fixtures, net	13,105,046	10,828,741
Patent rights, net	2,778,522	2,885,024
Goodwill	1,095,355	1,095,355
Other assets	326,056	325,955
Total Assets	\$ 58,669,743	\$ 68,772,762
Liabilities and Stockholders Equity		
Current Liabilities:		
Accounts payable	\$ 8,852,636	\$ 10,071,504
Accrued expenses and other liabilities	4,759,033	5,635,559
Deferred revenue	7,435,518	8,520,517
Total current liabilities	21,047,187	24,227,580
Deferred revenue long term	2,472,483	3,349,026
Total liabilities	23,519,670	27,576,606
Stockholders Equity:		
Preferred Stock: \$0.01 par, authorized 3,000,000 shares, none outstanding		
Common Stock: \$0.01 par; authorized 200,000,000 shares; 131,751,105 and 131,743,365 issued and outstanding at March 31, 2015 and December 31,	1,317,511	1,317,433

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

2014, respectively		
Additional paid-in capital	249,761,515	249,032,066
Accumulated deficit	(215,235,330)	(208,447,656)
Accumulated other comprehensive loss	(693,623)	(705,687)
	35,150,073	41,196,156
Total Liabilities and Stockholders' Equity	\$ 58,669,743	\$ 68,772,762

See accompanying notes to condensed consolidated financial statements.

Table of Contents

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

	For the Three Months Ended March 31,	
	2015	2014
Revenue:		
Product sales	\$ 4,623,130	\$ 1,805,302
Development revenue	2,388,403	1,421,149
Licensing revenue	883,009	928,129
Royalties	453,495	1,047,615
Total revenue	8,348,037	5,202,195
Cost of revenue:		
Cost of product sales	1,957,573	1,017,437
Cost of development revenue	1,717,156	159,308
Total cost of revenue	3,674,729	1,176,745
Gross profit	4,673,308	4,025,450
Operating expenses:		
Research and development	4,377,981	4,533,626
Selling, general and administrative	7,037,290	8,300,168
Total operating expenses	11,415,271	12,833,794
Operating loss	(6,741,963)	(8,808,344)
Other income (expense)	(45,711)	13,739
Net loss	\$ (6,787,674)	\$ (8,794,605)
Basic and diluted net loss per common share	\$ (0.05)	\$ (0.07)
Basic and diluted weighted average common shares outstanding	131,744,741	129,656,257

See accompanying notes to condensed consolidated financial statements.

Table of Contents

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

	For the Three Months Ended March 31,	
	2015	2014
Net loss	\$ (6,787,674)	\$ (8,794,605)
Foreign currency translation adjustment	12,064	2,191
Comprehensive loss	\$ (6,775,610)	\$ (8,792,414)

See accompanying notes to condensed consolidated financial statements.

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

	For the Three Months Ended March 31,	
	2015	2014
Cash flows from operating activities:		
Net loss	\$ (6,787,674)	\$ (8,794,605)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	378,555	224,753
Stock-based compensation expense	733,695	621,427
Amortization of premiums and discounts	1,414	15,111
Changes in operating assets and liabilities:		
Accounts receivable	(694,369)	(2,613,670)
Inventories	(37,074)	(644,961)
Prepaid expenses and other current assets	(684,112)	710,189
Deferred costs	205,257	(169,259)
Accounts payable	(392,895)	(1,144,516)
Accrued expenses and other current liabilities	(1,415,479)	(939,596)
Deferred revenue	(1,965,551)	5,774,239
Net cash used in operating activities	(10,658,233)	(6,960,888)
Cash flows from investing activities:		
Purchases of equipment, molds, furniture and fixtures	(1,889,615)	(128,701)
Additions to patent rights	(927,631)	(42,259)
Proceeds from maturities of investment securities	3,000,000	6,000,000
Net cash provided by investing activities	182,754	5,829,040
Cash flows from financing activities:		
Proceeds from exercise of stock options and warrants		1,236,935
Taxes paid related to net share settlement of equity awards	(11,277)	(115,123)
Net cash provided by (used in) financing activities	(11,277)	1,121,812
Effect of exchange rate changes on cash and cash equivalents	891	250
Net decrease in cash and cash equivalents	(10,485,865)	(9,786)
Cash and cash equivalents:		
Beginning of period	34,028,889	39,067,236

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

End of period	\$	23,543,024	\$	39,057,450
Noncash investing activities:				
Purchases of equipment, molds, furniture and fixtures recorded in accounts payable and accrued expenses	\$	1,754,053	\$	739,713
Additions to patent rights recorded in accounts payable and accrued expenses		32,629		771,100

See accompanying notes to condensed consolidated financial statements.

Table of Contents

ANTARES PHARMA, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

1. Description of Business

Antares Pharma, Inc. (Antares or the Company) is an emerging, specialty pharmaceutical company that focuses on developing and commercializing self-administered parenteral pharmaceutical products and technologies. Antares has numerous partnerships with pharmaceutical companies as well as multiple internal product development programs.

The Company develops and manufactures for itself and with partners, novel, pressure-assisted injectors, with and without needles, which allow patients to self-inject drugs. Antares has developed variations of the needle-free injector by adding a small shielded needle to a pre-filled, single-use disposable injector, called the Vibex® pressure assisted auto injection system. This system is an alternative to the needle-free system for use with injectable drugs in unit dose containers and is suitable for branded and generic injectables. Antares also developed a disposable multi-dose pen injector for use with standard cartridges. The Company has entered into multiple licenses for these devices mainly in the United States (U.S.), Europe and Canada with Teva Pharmaceutical Industries, Ltd. (Teva).

The Company has developed the Vibex® auto injector for its product OTREXUP® (methotrexate) injection. In February 2014, Antares launched OTREXUP® (methotrexate) injection, which is the first subcutaneous methotrexate for once weekly self-administration with an easy-to-use, single dose, disposable auto injector approved by the U.S. Food and Drug Administration (FDA). OTREXUP® is indicated for adults with severe active rheumatoid arthritis (RA), children with active polyarticular juvenile idiopathic arthritis and adults with severe recalcitrant psoriasis (psoriasis). To date, Antares has received FDA approval for dosage strengths of 7.5 mg, 10 mg, 15 mg, 20 mg and 25 mg of OTREXUP®. The Company has worldwide marketing rights for OTREXUP® and commercializes OTREXUP® on its own in the U.S. for the treatment of RA. The Company provided LEO Pharma A/S (LEO Pharma) an exclusive license to commercialize OTREXUP® in the U.S. for the treatment of psoriasis. As discussed in Note 8 to the Condensed Consolidated Financial Statements, the agreement with LEO Pharma was terminated in April 2015 and will end on June 23, 2015, at which time the Company will regain the marketing rights in the U.S. for OTREXUP® the treatment of psoriasis.

The Company is currently conducting clinical studies of Vibex® QuickShot® Testosterone (QS T), for testosterone replacement therapy. On February 25, 2015, Antares announced positive top-line pharmacokinetic results that showed that the primary endpoint was achieved in the Company's ongoing, multi-center, phase 3 clinical study (QST-13-003) evaluating the efficacy and safety of testosterone enanthate administered once-weekly by subcutaneous injection using the QuickShot® auto injector in testosterone deficient adult males. The Company also has initiated manufacturing development work for QS M, a combination product for an undisclosed central nervous system (CNS) indication.

Antares also is developing VIBEX® Sumatriptan for the acute treatment of migraines which if approved will be distributed by Teva. In January 2015, the Company received a complete response letter from FDA regarding its Abbreviated New Drug Application (ANDA) for VIBEX® Sumatriptan, providing revisions to labelling and citing minor deficiencies, and the Company submitted its response in March 2015. We have begun commercial scale tooling and mold fabrication in anticipation of potential approval and launch.

The Company's development projects in collaboration with Teva include VIBEX[®] epinephrine, an exenatide multi-dose pen, and another undisclosed multi-dose pen. In December 2014, Teva submitted the final amendment to the VIBEX[®] epinephrine ANDA, and FDA accepted Teva's filing of an ANDA in October 2014 for exenatide, formerly referred to as Teva Pen 2.

The Company also makes a reusable, needle-free, spring-action injector device known as the Tjet[®] and Zomajet[®], which is marketed for use with human growth hormone (hGH). Antares has had success in achieving distribution of this device for use with hGH through licenses to pharmaceutical partners, Ferring Pharmaceuticals Inc. and Ferring B.V. (together Ferring) and JCR Pharmaceuticals Co., Ltd. (JCR), and it has resulted in product sales and royalties. Ferring commercializes the Company's needle-free injection system with their 4 mg and 10 mg hGH formulations marketed as Zomajet[®] 2 Vision and Zomajet[®] Vision X worldwide. Ferring purchased the U.S. rights to TEV-TROPIN[®] (Teva's hGH),

Table of Contents

and Tjet® in December 2014 from Teva. In March 2015, Ferring received FDA approval of a name change enabling TEV-TROPIN® to be marketed in the U.S. as ZOMACTON (somatropin [rDNA origin]) for injection and the Tjet® needle-free delivery system to be marketed in the U.S. as ZOMA-Jet . Also in March 2015, Ferring received approval from the FDA to market the 10 mg needle free injector device which, along with certain consumables, is supplied by Antares to Ferring. Distribution of growth hormone injectors occurs in the U.S., Europe, Japan and other Asian countries through our pharmaceutical company relationships.

The Company also has a portfolio of gel-based products which are commercialized through various partners. Antares received FDA approval in December 2011 for an oxybutynin gel product, Gelnique 3% , for the treatment of overactive bladder (OAB). The Company has a licensing agreement with Actavis plc (Actavis) under which Actavis is currently marketing Gelnique 3% in the U.S. Elestrif® (estradiol gel) is currently marketed by Meda Pharmaceuticals, Inc. (Meda) in the U.S. for the treatment of moderate-to-severe vasomotor symptoms associated with menopause.

2. Basis of Presentation and Significant Accounting Policies

The accompanying unaudited condensed 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 condensed 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, 2014. Operating results for the three months ended March 31, 2015 are not necessarily indicative of the results that may be expected for the year ending December 31, 2015.

Certain prior year amounts have been reclassified in the condensed consolidated financial statements to conform to the current year presentation. These reclassifications were made to present selling, general and administrative expenses in one line in the consolidated statements of operations. In prior years, sales and marketing expenses and general and administrative expenses were presented in separate lines. 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 March 31, 2015, the short-term investments had a fair value of \$3,001,875 and a carrying value of \$3,001,024. At December 31, 2014, the short-term investments had a fair value of \$6,005,040 and a carrying value of \$6,002,438.

Inventories

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

	March 31, 2015	December 31, 2014
Inventories:		
Raw material	\$ 489,297	\$ 461,396
Work in process	2,216,966	3,896,837
Finished goods	3,190,735	1,501,691
	\$ 5,896,998	\$ 5,859,924

Table of Contents

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 are 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, 2015 and December 31, 2014, approximately \$1,800,000 of external legal patent defense costs were capitalized within patent rights, net.

Product Revenue

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

The Company recognized \$3,004,309 and \$212,845 in OTREXUP[®] product revenue from U.S. customers for the three months ended March 31, 2015 and 2014, respectively, which is net of estimated wholesaler discounts, prompt pay discounts, chargebacks, rebates and patient discount programs. The Company had a deferred revenue balance of \$1,067,165 and \$1,061,947 at March 31, 2015 and December 31, 2014, respectively, for OTREXUP[®] 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[®] 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 our agreements with customers and third-party payors and the levels of inventory within the distribution channels that may result in future rebates or discounts taken. In certain cases, such as patient support programs, the Company recognizes the cost of patient discounts as a reduction of revenue based on estimated utilization. If actual future results vary, it may be necessary to adjust these estimates, which could have an effect on product revenue in the period of adjustment. Product sales allowances include:

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

Table of Contents

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, 2015, 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.

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

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

3. 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 March 31, 2015, the Plan had 4,016,156 shares available for grant. Stock option exercises are satisfied through the issuance of new shares.

Table of Contents*Stock Options*

A summary of stock option activity under the Plan as of March 31, 2015, and the changes during the three 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, 2014	7,245,485	2.25		
Granted	275,000	2.59		
Exercised				
Cancelled/Forfeited	(19,959)	3.16		
Outstanding at March 31, 2015	7,500,526	2.26	6.6	5,249,105
Exercisable at March 31, 2015	5,230,969	1.96	5.4	4,970,719

In March 2015, the Company granted to its executive officers, as consideration for 2014 performance, a total of 245,000 stock options, which vest quarterly over a one-year period. The per share weighted average fair values of all options granted during the first three months of 2015 and 2014 were estimated as \$1.35 and \$2.55, respectively, on the date of grant using the Black-Scholes option pricing model based on the assumptions noted in the table below. Expected volatilities are based on the historical volatility of the Company's stock price. The weighted average expected life is based on both historical and anticipated employee behavior.

	March 31,	
	2015	2014
Risk-free interest rate	1.5%	1.7%
Annualized volatility	54.8%	61.7%
Weighted average expected life, in years	6.0	6.0
Expected dividend yield	0.0%	0.0%

There were no stock option exercises in the first three months of 2015. 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.

Total recognized compensation expense for stock options was approximately \$641,000 and \$360,000 for the first three months of 2015 and 2014, respectively. As of March 31, 2015, there was approximately \$3,133,000 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.

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. There were no discretionary grants of common stock in the first three months of 2015. In the first three months of 2014, there were 150,000 shares of common stock granted to members of executive management as bonus compensation for achievements 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. In 2015 and 2014, no shares

Table of Contents

were granted to the directors, as all directors' compensation was paid in cash and stock options. Expense is recognized on a straight line basis over the one-year period in which the compensation is earned. Expense recognized in connection with shares granted to directors was \$179,600 in the three-month period ended March 31, 2014.

Long Term Incentive Program (LTIP)

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

The stock options have a ten-year term, have an exercise price equal to the closing price of the Company's common stock on the date of grant, vest in quarterly installments over three years, were otherwise granted on the same standard terms and conditions as other stock options granted pursuant to the Plan and are included in the stock options table above.

The RSUs vest in three equal annual installments. Expense recognized in the first three months of 2015 and 2014 in connection with the RSUs was approximately \$57,800 and \$51,000, respectively.

The PSU 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. The 2014 awards included PSUs that will be earned based on the Company's total shareholder return (TSR) as compared to the Nasdaq Biotechnology Index (NBI) at the end of the performance period, which performance period is January 1, 2014 to December 31, 2016. These PSUs were granted with a grant date fair value of \$2.64. Depending on the outcome of the performance goal, a recipient may ultimately earn a number of shares greater or less than their target number of shares granted, ranging from 0% to 150% of the PSUs granted. The fair value of the TSR PSUs granted in May 2014 was determined using a Monte Carlo simulation and utilized the following inputs and assumptions:

Closing stock price on grant date	\$ 3.09
Performance period starting price	\$ 4.08
Term of award (in years)	2.59
Volatility	50.87%
Risk-free interest rate	0.61%
Expected dividend yield	0.00%
Fair value per TSR PSU	\$ 2.64

The performance period starting price is measured as the average closing price over the last 20 trading days prior to the performance period start. The Monte Carlo simulation model also assumed correlations of returns of the prices of the Company's common stock and the common stocks of the NBI companies and stock price volatilities of the NBI companies.

The fair value of the target number of shares that can be earned under the TSR PSUs is being recognized as compensation expense over the performance period, and expense of \$31,500 was recognized in connection with this award in the first three months of 2015. Expense recognized in the first three months of 2015 and 2014 in connection with other PSU awards for defined performance goals considered probable of achievement was \$3,600 and \$31,000, respectively.

At March 31, 2015 and December 31, 2014, there were 463,542 PSUs outstanding with a weighted average fair value of \$3.08. At March 31, 2015 and December 31, 2014, there were 231,124 restricted shares or RSUs outstanding, with a weighted average fair value of \$3.07. There were no PSUs or RSUs granted, vested, forfeited or expired in the first quarter of 2015.

Table of Contents

Shares issued in the first three months of 2015 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 4,779 and 25,545 in the three-month periods ended March 31, 2015 and 2014, 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 \$11,277 and \$115,123 in the three-month periods ended March 31, 2015 and 2014, 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. There were no warrants outstanding at March 31, 2015 or December 31, 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 7,500,526 and 7,137,814 at March 31, 2015 and 2014, respectively. The table below discloses the basic and diluted loss per common share.

	Three Months Ended March 31,	
	2015	2014
Net loss	\$ (6,787,674)	\$ (8,794,605)
Basic and diluted weighted average common shares outstanding	131,744,741	129,656,257
Basic and diluted net loss per common share	\$ (0.05)	\$ (0.07)

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:

**Three Months Ended
March 31,**

	2015	2014
U.S.	\$ 6,762,776	\$ 3,914,659
Europe	1,471,416	1,085,096
Other	113,845	202,440
	\$ 8,348,037	\$ 5,202,195

Revenues by product type:

	Three Months Ended March 31,	
	2015	2014
Injection devices and supplies	\$ 8,000,722	\$ 4,806,782
Transdermal products	347,315	395,413
	\$ 8,348,037	\$ 5,202,195

Table of Contents

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

	Three Months Ended	
	March 31,	
	2015	2014
Teva	\$ 2,332,815	\$ 2,448,287
McKesson (1)	1,899,705	53,404
Ferring	1,471,416	1,085,096
AmerisourceBergen (1)	875,145	72,287
LEO Pharma	857,143	857,143

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

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

In November 2013, the Company entered into a promotion and license agreement with LEO Pharma. Under this agreement, the Company granted LEO Pharma the exclusive right to promote OTREXUP to dermatologists for symptomatic control of psoriasis in adults in the U.S. LEO Pharma 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 Pharma a non-refundable upfront payment of \$5.0 million and a milestone payment of \$5.0 million. The Company pays LEO Pharma a percentage of net sales generated in dermatology and records the payments to LEO Pharma as sales and marketing expense. The deliverables in the agreement have been accounted for as a single unit of accounting and each of the payments has been allocated to these deliverables and are being recognized as revenue over the 35 month estimated life of the agreement. The Company recognized \$857,000 of revenue in each of the three month periods ended March 31, 2015 and 2014, and recorded deferred revenue in connection with this agreement of \$5,143,000 and \$6,000,000 at March 31, 2015 and December 31, 2014, respectively. As discussed in Note 8, in April 2015, the agreement was terminated, and the Company regained U.S. marketing rights to OTREXUP for the psoriasis indication.

7. 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 U.S. 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. 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.

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

Antares filed an appeal of the denial of the motion for preliminary injunction with the U.S. Court of Appeals for the Federal Circuit, and in February 2015, that motion was denied. In 2014 and through the three months ended March 31, 2015, a total of approximately \$1,800,000 in legal costs in connection with this suit has been capitalized.

On March 7, 2014, Medac filed suit against Antares, LEO Pharma, Inc. and its parent company, LEO Pharma A/S (LEO Pharma, Inc. together with LEO Pharma A/S, the LEO Entities) in the U.S. District Court for the District of New Jersey, alleging that Antares and the LEO Entities infringe Medac Pharma s

Table of Contents

U.S. Patent 8,664,231 (the '231 patent') that was issued by the U.S. Patent and Trademark Office on March 4, 2014. 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, and in January 2015, the PTAB decided to institute review of the '231 patent. Legal costs in connection with this suit and the inter partes review were expensed as incurred.

In April 2015, Antares, Medac and the LEO Entities entered into a settlement agreement pursuant to which all of the proceedings related to Antares' and Medac's respective patents mentioned above and the proceeding pending before the Technical Board of Appeal of the European Patent Office will be dismissed. The settlement agreement also provides for a royalty-free cross-license under the patents named in the proceedings and their families allowing the manufacture and sale of OTREXUP (methotrexate) injection and RASUVO in and for the U.S. As a result, the \$1,800,000 of capitalized legal costs will continue to be amortized over the estimated useful life of the patents.

8. Subsequent Events

As discussed in Note 7 above, in April 2015, Antares, Medac and the LEO Entities entered into a settlement agreement pursuant to which all of the proceedings related to Antares' and Medac's respective patents discussed in Note 7 above and the proceeding pending before the Technical Board of Appeal of the European Patent Office will be dismissed.

On April 27, 2015, the Company announced that it regained U.S. marketing rights to OTREXUP™ for the psoriasis indication through the termination of its exclusive promotion and marketing agreement with LEO Pharma for detailing OTREXUP™ to dermatologists for psoriasis. The collaboration will end on June 23, 2015. The Company previously received a total of \$10 million in cash from LEO Pharma for the right to commercialize OTREXUP™ to dermatologists, which was recorded as deferred revenue and was being amortized to licensing revenue over a three-year period. As a result of the termination of the agreement with LEO Pharma, the Company expects to recognize the remaining unamortized balance of the deferred revenues of \$5,142,857 as licensing revenue in the second quarter of 2015.

On May 11, 2015, the Company completed an underwritten offering of 23,000,000 shares of its common stock, which includes 3,000,000 shares pursuant to the underwriters' exercise of their option in full, at a price to the public of \$2.00 per share. The Company received net proceeds of approximately \$42.8 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company. The Company intends to use the net proceeds from the offering for general corporate purposes including business development, in-licensing and acquisitions.

Table of Contents

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) injection for subcutaneous use;

our expectations regarding product development and potential approval by the United States (U.S.) Food and Drug Administration (FDA) of Vibex® QuickShot (Vibex® QS T) (testosterone injection);

our expectations regarding continued product development with Teva Pharmaceutical Industries, Ltd. (Teva);

our expectations regarding product development and potential FDA approval of Vibex® Sumatriptan (sumatriptan injection);

our expectations regarding product development and potential FDA approval of Vibex® epinephrine pen (epinephrine auto injector);

our expectations regarding trends in pharmaceutical drug delivery characteristics;

our anticipated continued reliance on contract manufacturers to manufacture our products;

our sales and marketing plans;

product development and commercialization plans regarding our other products and product candidates;

our plans regarding potential manufacturing and marketing partners;

our future cash flow and our ability to support our operations;

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

our expectations regarding the year ending December 31, 2015.

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.

Table of Contents

In addition, you should refer to the Risk Factors section of our Annual Report on Form 10-K for the year ended December 31, 2014 for a discussion of other factors that may cause our actual results to differ materially from those described by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements contained in this report will prove to be accurate and, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material.

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

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

Overview

Antares Pharma, Inc. (Antares, we, our, us or the Company) is an emerging, specialty pharmaceutical company 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 develop and manufacture for ourselves and with partners, novel, pressure-assisted injectors, with and without needles, which allow patients to self-inject drugs. We have developed variations of the needle-free injector by adding a small shielded needle to a pre-filled, single-use disposable injector, called the Vibex® pressure assisted auto injection system. This system is an alternative to the needle-free system for use with injectable drugs in unit dose containers and is suitable for branded and generic injectables. We also developed a disposable multi-dose pen injector for use with standard cartridges. We have entered into multiple licenses for these devices mainly in the United States, Europe and Canada with Teva.

We developed the Vibex® auto injector for our product OTREXUP (methotrexate) injection. In February 2014, we launched OTREXUP (methotrexate) injection, which 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), children with active polyarticular juvenile idiopathic arthritis and adults with severe recalcitrant psoriasis (psoriasis). To date, we have received FDA approval for dosage strengths of 7.5 mg, 10 mg, 15 mg, 20 mg and 25 mg of OTREXUP . We have worldwide marketing rights for OTREXUP and commercialize OTREXUP on our own in the U.S. for the treatment of RA. We have provided LEO Pharma A/S (LEO Pharma) an exclusive license to commercialize OTREXUP in the U.S. for the treatment of psoriasis. As discussed in Note 8 to the Condensed Consolidated Financial Statements, the agreement with LEO Pharma was terminated in April 2015 and will end on June 23, 2015, at which time we will regain the marketing rights in the U.S. for the treatment of psoriasis.

We are currently conducting clinical studies of Vibex® QS T, for testosterone replacement therapy. On February 25, 2015, we announced positive top-line pharmacokinetic results that showed that the primary endpoint was achieved in

the Company's ongoing, multi-center, phase 3 clinical study (QST-13-003) evaluating the efficacy and safety of testosterone enanthate administered once-weekly by subcutaneous injection using the QuickShot® auto injector in testosterone deficient adult males. We also have initiated manufacturing development work for QS M, a combination product for an undisclosed central nervous system (CNS) indication.

We also are developing VIBEX® Sumatriptan for the acute treatment of migraines which if approved will be sold by Teva. In January 2015, we received a complete response letter from FDA regarding our Abbreviated New Drug Application (ANDA) for VIBEX® Sumatriptan, providing revisions to labelling and citing minor deficiencies, and we submitted our response to FDA in March 2015. We have begun commercial scale tooling and mold fabrication in anticipation of potential approval and launch.

Table of Contents

Our development projects in collaboration with Teva include VIBEX® epinephrine, an exenatide multi-dose pen, and another undisclosed multi-dose pen. In December 2014, Teva submitted the final amendment to the VIBEX® epinephrine pen ANDA, and FDA accepted Teva's filing of an ANDA in October 2014 for exenatide, formerly referred to as Teva Pen 2.

We also make a reusable, needle-free, spring-action injector device known as the Tjet® and Zomajet®, which is marketed for use with human growth hormone (hGH). We have had success in achieving distribution of our device for use with hGH through licenses to pharmaceutical partners, Ferring Pharmaceuticals Inc. and Ferring B.V. (together Ferring) and JCR Pharmaceuticals Co., Ltd. (JCR), and it has resulted in product sales and royalties. Ferring commercializes our needle-free injection system with their 4 mg and 10 mg hGH formulations marketed as Zomajet® 2 Vision and Zomajet® Vision X worldwide. Ferring purchased the U.S. rights to TEV-TROPIN® (Teva's hGH) and Tjet®, in December 2014 from Teva. In March 2015, Ferring received FDA approval of a name change enabling TEV-TROPIN® to be marketed in the U.S. as ZOMACTON (somatropin [rDNA origin]) for injection and the Tjet® needle-free delivery system to be marketed in the U.S. as ZOMA-Jet. Also in March 2015, Ferring received approval from the FDA to market the 10 mg needle free injector device which, along with certain consumables, is supplied by Antares to Ferring. Distribution of growth hormone injectors occurs in the U.S., Europe, Japan and other Asian countries through our pharmaceutical company relationships.

We also have a portfolio of gel-based products which are commercialized through various partners. We received FDA approval in December 2011 for an oxybutynin gel product, Gelnique 3% , for the treatment of overactive bladder (OAB). We have a licensing agreement with Actavis plc (Actavis) under which Actavis is currently marketing Gelnique 3% in the U.S. Elestri® (estradiol gel) is currently marketed by Meda Pharmaceuticals, Inc. (Meda) in the U.S. for the treatment of moderate-to-severe vasomotor symptoms associated with menopause.

We have reported a net loss of \$6,787,674 for the three months ended March 31, 2015. Operating results for the three months ended March 31, 2015 are not necessarily indicative of the results that may be expected for the year ending December 31, 2015.

Results of Operations*Three Months Ended March 31, 2015 and 2014**Revenues*

	Three Months Ended March 31,	
	2015	2014
OTREXUP	\$ 3,004,309	\$ 212,845
Needle-free injector devices and components	1,420,753	1,256,471
Auto injector and pen injector devices	198,068	335,986
Total product sales	4,623,130	1,805,302
Development revenue	2,388,403	1,421,149
Licensing revenue	883,009	928,129
Royalties	453,495	1,047,615
Total revenue	\$ 8,348,037	\$ 5,202,195

OTREXUP

In 2014, we began recognizing product revenues from sales of OTREXUP made by us and by LEO Pharma under our license and promotion agreement. We began detailing OTREXUP to rheumatologists in February 2014, and LEO Pharma began detailing to dermatologists in mid-March 2014. In the three months ended March 31, 2015 and 2014, we recognized OTREXUP net product sales of \$3,004,309 and \$212,845, respectively, based on prescription data.

Table of Contents

We sell OTREXUP[®] in a package of four pre-filled, single-dose disposable auto injectors to wholesale pharmaceutical distributors, our customers. Sales to our customers are subject to specified rights of return. We currently defer recognition of revenue on product shipments of OTREXUP[®] to our customers until the right of return no longer exists, which occurs at the earlier of the time OTREXUP[®] units are dispensed through patient prescriptions or expiration of the right of return.

We had a deferred revenue balance of \$1,067,165 and \$1,061,947 at March 31, 2015 and December 31, 2014, respectively, for OTREXUP[®] 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.

Needle-free injector devices and components

Our sales of reusable needle-free injector devices and disposable components were generated primarily from sales to Ferring. Ferring uses our needle-free injector with their 4 mg and 10 mg hGH formulations marketed as Zomajet[®] 2 Vision and Zomajet[®] Vision X, respectively, in Europe and Asia. In the fourth quarter of 2014, Ferring purchased the U.S. rights to Tev-Tropin[®] from Teva. Teva used our Tjet[®] needle-free device with their 5 mg hGH Tev-Tropin[®] marketed in the U.S. In April 2014, Teva initiated a recall of the drug product, Tev-Tropin[®] (not the device which we supply) and had halted sales of the drug earlier that year. The recall had a negative effect on the level of product sales to Teva. In March 2015, Ferring received FDA approval of a name change enabling its newly acquired recombinant human growth hormone to be marketed in the U.S. as ZOMACTON (somatropin [rDNA origin]) for injection, and the needle-free delivery system to be marketed in the U.S. as ZOMA-Jet. Also in March 2015, Ferring received approval from the FDA to market the 10 mg needle free injector device. Ferring has indicated that ZOMACTON is expected to be available in the U.S. in the second quarter of 2015 and that the ZOMA-Jet needle-free devices are expected to be available later in 2015. However, we do not control our partners' inventory levels of our hGH injectors or disposable components and this can cause significant fluctuations in product sales.

Auto injector and pen injector devices

Revenues in the three months ended March 31, 2015 and 2014 included \$198,068 and \$335,986, respectively, of sales of pre-commercial pen injector devices to Teva for use with an undisclosed product (Pen 1). Teva has placed a purchase order for auto injectors used in their generic epinephrine product in anticipation of a possible launch. We began shipping these auto injectors to Teva in the second quarter of 2015.

Development Revenue

Development revenues typically represent amounts earned under arrangements with partners in which we develop new products on their behalf. Frequently, we receive payments from our partners that are initially deferred and recognized as revenue over a development period or upon completion of defined deliverables. Development revenue was \$2,388,403 and \$1,421,149 for the three month periods ended March 31, 2015 and 2014, respectively. The development revenue in each period was primarily related to the Teva auto injector and pen injector programs.

Licensing Revenue

Licensing revenues represent the amounts recognized from up-front or milestone payments received from partners that are initially deferred. Licensing revenue was \$883,009 and \$928,129 for the three month periods ended March 31,

2015 and 2014, respectively. The licensing revenue in each period was primarily due to revenue recognized in connection with our license and promotion agreement with LEO Pharma executed in November of 2013, which is being recognized over a 35-month period. As discussed in Note 8 to the Condensed Consolidated Financial Statements, the agreement with LEO Pharma was terminated in April 2015 and will end on June 23, 2015. As a result of the termination of the agreement with LEO Pharma, we expect to recognize the remaining unamortized balance of the deferred revenues of \$5,142,857 as licensing revenue in the second quarter of 2015.

Table of Contents*Royalties*

Royalty revenue was \$453,495 and \$1,047,615 for the three-month periods ended March 31, 2015 and 2014, respectively. We receive royalties from Ferring related to needle-free injector device sales, from Meda Pharmaceuticals, Inc. on sales of Elestrin[®] and from Actavis plc on sales of Gelnique 3%. In 2014, we also received royalties from Teva for hGH sales. In the first three months of 2015 and 2014, our royalties related to needle-free injector device sales and/or hGH sales accounted for approximately 22% and 66%, respectively, of our overall royalty revenue. The decrease in 2015 compared to 2014 was primarily the result of receiving no royalties from Teva after the first quarter of 2014. Our royalties from Teva were 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 2014 and had halted sales of the drug earlier in the year. In the fourth quarter of 2014, Ferring purchased the U.S. rights to Tev-Tropin[®] from Teva. In March 2015, Ferring received FDA approval of a name change enabling its newly acquired recombinant human growth hormone to be marketed in the U.S. as ZOMACTON (somatropin [rDNA origin]) for injection, and the needle-free delivery system to be marketed in the U.S. as ZOMA-Jet. Also in March 2015, Ferring received approval from the FDA to market the 10 mg needle free injector device. Ferring has indicated that ZOMACTON is expected to be available in the U.S. in the second quarter of 2015 and that the ZOMA-Jet needle-free devices are expected to be available later in 2015.

Cost of Revenues and Gross Margins

The cost of product sales includes product acquisition costs from third-party manufacturers and internal manufacturing overhead expenses. Cost of product sales were \$1,957,573 and \$1,017,437 for the three month periods ended March 31, 2015 and 2014, respectively, resulting in product gross margins of 58% and 44%, respectively. The product gross margin increase in 2015 compared to 2014 was the result of an increase in sales of OTREXUP[®], which is sold at a higher gross margin than our other products.

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 \$1,717,156 and \$159,308 for the three-month periods ended March 31, 2015 and 2014, respectively, resulting in gross margins of 28% and 89%, respectively. The cost of development revenue in each period was primarily related to revenue recognized under the Teva auto injector and pen injector programs. Development gross margins can vary significantly from period to period depending on the mix of development projects in each period.

Research and Development

Research and development expenses consist of external costs for studies and analysis activities, design work and prototype development, FDA fees, and salaries and other general operating expenses associated with research and development. Research and development expenses were \$4,377,981 and \$4,533,626 in the three-month periods ended March 31, 2015 and 2014, respectively. Research and development expenses in each period were driven primarily by external expenses in connection with development of Vibex[®] QST for testosterone replacement therapy.

Selling, General and Administrative

Selling, general and administrative expenses were \$7,037,290 and \$8,300,168 for the three-month periods ended March 31, 2015 and 2014, respectively. The decrease in 2015 was primarily due to a reduction in expenses related to OTREXUP[®] market research, product branding, commercialization and pre-commercialization activities.

Liquidity and Capital Resources

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

At March 31, 2015, our cash and investments totaled \$26,544,048, which consisted of cash and cash equivalents of \$23,543,024 and short-term investments of \$3,001,024. All investments are U.S. Treasury bills or U.S. Treasury notes which we intend to hold to maturity.

Table of Contents

On May 11, 2015, we completed an underwritten offering of 23,000,000 shares of our common stock, which includes 3,000,000 shares pursuant to the underwriters' exercise of their option in full, at a price to the public of \$2.00 per share. We received net proceeds of approximately \$42.8 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from the offering for general corporate purposes including business development, in-licensing and acquisitions.

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. If in the future we do not turn profitable or generate cash from operations as anticipated and additional capital is needed to support operations, we may be unable to obtain such financing, or obtain it on favorable terms, in which case we may be required to curtail development of new products, limit expansion of operations or accept financing terms that are not as attractive as we may desire.

*Cash Flows**Net Cash Used in Operating Activities*

Operating cash inflows are generated primarily from product sales, license and development fees and royalties. Operating cash outflows consist principally of expenditures for manufacturing costs, general and administrative costs, research and development projects including clinical studies, and sales and marketing activities. Net cash used in operating activities was \$10,658,233 and \$6,960,888 for the three months ended March 31, 2015 and 2014, respectively. The increase in cash used in operating activities in the first three months of 2015 compared to 2014 was primarily the result of a net decrease in cash of \$7,739,790 related to the change in deferred revenue. In the first quarter of 2015, the change in deferred revenue resulted in a decrease in cash of \$1,965,551 due primarily to the recognition of revenue related to Teva auto injector and pen injector development programs that exceeded amounts received. In the first quarter of 2014, the change in deferred revenue resulted in an increase in cash of \$5,774,239, primarily as a result of a \$5,000,000 milestone payment received from LEO Pharma. Partially offsetting the decrease in deferred revenue was a decrease in the net loss for the quarter of \$2,006,931 to \$6,787,674 for the first quarter of 2015 from \$8,794,605 for the first quarter of 2014, which was significantly affected by the decrease of \$1,262,878 in selling, general and administrative expenses due primarily to a decrease in expenses associated with the launch of OTREXUP[®] in 2014. Also offsetting the decrease in deferred revenue was a net decrease of \$1,783,141 in cash used in the first quarter of 2015 compared to 2014 in connection with the change in other operating assets and liabilities.

Net Cash Provided by Investing Activities

Net cash provided by investing activities in the first three months of 2015 and 2014 was \$182,754 and \$5,829,040, respectively. Cash used for purchases of equipment, molds, furniture and fixtures was \$1,889,615 in 2015 compared to \$128,701 in 2014, primarily related to Vibex[®] QS T commercial molds and assembly equipment. Additions to patent rights were \$927,631 in 2015 compared to \$42,259 in 2014. In the first three months of 2015 and 2014 we received proceeds of \$3,000,000 and \$6,000,000, respectively, from the maturity of 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 used in financing activities in the first three months of 2015 was \$11,277 compared to net cash provided by financing activities in the first three months of 2014 of \$1,121,812. In the first three months of 2014 we received proceeds of \$1,236,935 from the exercise of 545,000 warrants and 570,178 options, respectively. In the first three

months of 2015 and 2014, total payments for employees' income and employment tax obligations related to net share settlement of equity awards was \$11,277 and \$115,123, respectively.

Table of Contents

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.

On December 5, 2012, we conducted a pre-IND (Investigational New Drug application) meeting with the FDA as part of preparing to initiate clinical development of Vibex® QS T, establishing an agreed upon clinical path forward. In September 2013, we announced that the first patients were dosed in a clinical study evaluating the pharmacokinetics of testosterone enanthate administered weekly by subcutaneous injection at doses of 50 mg and 100 mg via the Vibex® QS T auto injector device in adult males with testosterone deficiency. The study enrolled 39 patients at nine investigative sites in the U.S. We announced our top-line results of this study on February 20, 2014. The results are considered positive in that Vibex® QS T treatment resulted in most patients achieving average levels of testosterone within the normal range from the first dose onward. Vibex® QS T was also safe and well-tolerated by all dosed patients.

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

On January 13, 2015, we announced that we received written recommendations from the FDA related to our clinical development program for QS T. The recommendations received were in response to various clinical, Chemistry, Manufacturing and Controls and user study submissions that we made through November 2014. We believe that we have already factored many of the recommendations cited in the advice letter into the protocol of the ongoing phase III study and into the protocols for planned human use studies as a result of guidance provided by FDA at the May 2014 Type C meeting. Based on a single reported occurrence of hives in our phase II study, which the FDA characterized as an apparent allergic reaction, as well as the known safety experience with other parenteral testosterone products, the FDA recommended that we create a larger safety database, including approximately 350 subjects exposed to QS T with 200 subjects exposed for six months and 100 subjects exposed for a year. We do not believe that the adverse event of hives reported in the phase II study was related to study drug. Based on the number of subjects in previous studies and in the current phase III study, we anticipate that we may need approximately 70 additional subjects exposed to QS T for six months. We are assessing the FDA's comments in the advice letter and their impact on the timing of the filing of a NDA for QS T with the FDA. The timing, cost and design of the study to obtain the additional 70 subjects and data required will be determined based on further discussion with the FDA. We submitted our response to FDA's written recommendations in early March 2015.

Table of Contents

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

Population/Analysis	C_{avg} Lower limit of the 95% 2-sided C. I.	C_{avg} % in range 300 1100 ng/dL n (%)	C_{max} <1500 ng/dL n (%)	C_{max} >1800 ng/dL n (%)
	Primary analysis* N=150	87.3%	139 (92.7%)	137 (91.3%)**
Completers N=137	94.8%	135 (98.5%)	137 (100%)	0%
Protocol-Required Outcomes	365%	75%	385%	5%

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

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

Overall, the regimen demonstrated a mean (\pm standard deviation) steady state concentration of testosterone of 553.3 \pm 127.3 ng/dL at 12 weeks.

Participants in the study will remain on QS T and will be followed for an additional 40 weeks, and the collection of safety data is ongoing. One hundred fifty patients have received at least one dose of study drug. To date, there has been one reported death, which was caused by suicide, and one serious adverse event (SAE) of hospitalization for worsening depression. This patient received a single dose of QS T, and the SAE was not considered to be related to study drug. Thus far, there have been no reported adverse events consistent with urticaria (hives).

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 use with exenatide and one undisclosed product. 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 entering the commercial stage of development. 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.

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 2015, 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 by Teva 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 operating costs related to managing our research and development projects.

Off-Balance Sheet Arrangements

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

Critical Accounting Policies

We have identified certain of our significant accounting policies that we consider particularly important to the portrayal of our results of operations and financial position and which may require the application of a higher level of judgment by management and, as a result, are subject to an inherent level of uncertainty. These policies are characterized as critical accounting policies and address revenue recognition 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, 2014.

Table of Contents**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.

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 March 31, 2015 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

Table of Contents

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

Internal Control over Financial Reporting

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

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART II - OTHER INFORMATION*Item 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, 2014, 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.

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

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.

Table of Contents

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 11, 2015

/s/ Eamonn Hobbs
Eamonn Hobbs
President and Chief Executive Officer
(Principal Executive Officer)

May 11, 2015

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