

ANTARES PHARMA, INC.  
Form 10-Q  
August 07, 2013  
[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 June 30, 2013

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

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

(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 August 1, 2013 was 127,158,925.

**Table of Contents**

**ANTARES PHARMA, INC.**

**INDEX**

	PAGE
<b><u>PART I. FINANCIAL INFORMATION</u></b>	
<b><u>Item 1. Financial Statements</u></b>	
<u>Consolidated Balance Sheets, as of June 30, 2013 (Unaudited) and December 31, 2012</u>	3
<u>Consolidated Statements of Operations (Unaudited) for the three months and six months ended June 30, 2013 and 2012</u>	4
<u>Consolidated Statements of Comprehensive Loss (Unaudited) for the three months and six months ended June 30, 2013 and 2012</u>	5
<u>Consolidated Statements of Cash Flows (Unaudited) for the six months ended June 30, 2013 and 2012</u>	6
<u>Notes to Consolidated Financial Statements (Unaudited)</u>	7
<b><u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b>	13
<b><u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u></b>	19
<b><u>Item 4. Controls and Procedures</u></b>	20
<b><u>PART II. OTHER INFORMATION</u></b>	
<b><u>Item 1A. Risk Factors</u></b>	21
<b><u>Item 6. Exhibits</u></b>	21
<b><u>SIGNATURES</u></b>	22

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

	<b>June 30, 2013 (Unaudited)</b>	<b>December 31, 2012</b>
<b>Assets</b>		
Current Assets:		
Cash and cash equivalents	\$ 35,914,972	\$ 52,097,064
Short-term investments	33,099,847	21,112,623
Accounts receivable	4,330,136	2,228,650
Inventories	1,028,427	1,002,703
Deferred costs	757,037	755,159
Prepaid expenses and other current assets	868,064	463,033
<b>Total current assets</b>	<b>75,998,483</b>	<b>77,659,232</b>
Equipment, molds, furniture and fixtures, net	5,291,484	3,583,104
Patent rights, net	1,134,442	1,123,652
Goodwill	1,095,355	1,095,355
Long-term investments	6,009,232	12,015,906
Other assets	61,056	49,361
<b>Total Assets</b>	<b>\$ 89,590,052</b>	<b>\$ 95,526,610</b>
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	\$ 5,180,913	\$ 2,864,507
Accrued expenses and other liabilities	2,782,564	2,916,700
Deferred revenue	1,288,212	2,157,016
<b>Total current liabilities</b>	<b>9,251,689</b>	<b>7,938,223</b>
Deferred revenue - long term	893,995	1,037,795
<b>Total liabilities</b>	<b>10,145,684</b>	<b>8,976,018</b>
Stockholders' Equity:		
Preferred Stock: \$0.01 par, authorized 3,000,000 shares, none outstanding		
Common Stock: \$0.01 par; authorized 150,000,000 shares; 127,053,425 and 125,949,024 issued and outstanding at June 30, 2013 and December 31, 2012, respectively	1,270,534	1,259,490
Additional paid-in capital	240,158,492	238,745,612
Accumulated deficit	(161,300,869)	(152,789,165)
Accumulated other comprehensive loss	(683,789)	(665,345)
	79,444,368	86,550,592
<b>Total Liabilities and Stockholders' Equity</b>	<b>\$ 89,590,052</b>	<b>\$ 95,526,610</b>

See accompanying notes to consolidated financial statements.



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

	For the Three Months Ended		For the Six Months Ended	
	2013	June 30, 2012	2013	June 30, 2012
<b>Revenue:</b>				
Product sales	\$ 4,512,891	\$ 3,211,955	\$ 7,005,367	\$ 5,706,065
Development revenue	588,164	737,409	1,381,874	3,723,485
Licensing revenue	68,662	109,093	138,007	734,912
Royalties	667,827	465,485	1,840,518	1,224,022
<b>Total revenue</b>	<b>5,837,544</b>	<b>4,523,942</b>	<b>10,365,766</b>	<b>11,388,484</b>
<b>Cost of revenue:</b>				
Cost of product sales	3,182,767	2,028,530	4,610,408	3,397,158
Cost of development revenue	297,915	502,581	897,417	1,124,784
<b>Total cost of revenue</b>	<b>3,480,682</b>	<b>2,531,111</b>	<b>5,507,825</b>	<b>4,521,942</b>
<b>Gross profit</b>	<b>2,356,862</b>	<b>1,992,831</b>	<b>4,857,941</b>	<b>6,866,542</b>
<b>Operating expenses:</b>				
Research and development	4,395,528	2,482,785	7,468,213	5,359,947
Sales and marketing	1,158,236	187,594	2,039,489	290,886
Business development	188,049	231,933	344,715	564,708
General and administrative	1,745,719	1,881,056	3,539,483	3,538,597
<b>Total operating expenses</b>	<b>7,487,532</b>	<b>4,783,368</b>	<b>13,391,900</b>	<b>9,754,138</b>
<b>Operating loss</b>	<b>(5,130,670)</b>	<b>(2,790,537)</b>	<b>(8,533,959)</b>	<b>(2,887,596)</b>
Other income (expense)	27,414	(16,535)	22,255	6,130
<b>Net loss</b>	<b>\$ (5,103,256)</b>	<b>\$ (2,807,072)</b>	<b>\$ (8,511,704)</b>	<b>\$ (2,881,466)</b>
<b>Basic and diluted net loss per common share</b>	<b>\$ (0.04)</b>	<b>\$ (0.03)</b>	<b>\$ (0.07)</b>	<b>\$ (0.03)</b>
<b>Basic and diluted weighted average common shares outstanding</b>	<b>126,462,677</b>	<b>104,551,742</b>	<b>126,285,677</b>	<b>104,105,156</b>

See accompanying notes to consolidated financial statements.

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

	<b>For the Three Months Ended June 30,</b>		<b>For the Six Months Ended June 30,</b>	
	<b>2013</b>	<b>2012</b>	<b>2013</b>	<b>2012</b>
Net loss	\$ (5,103,256)	\$ (2,807,072)	\$ (8,511,704)	\$ (2,881,466)
Foreign currency translation adjustment	911	(64,945)	(18,444)	(105,448)
Comprehensive loss	\$ (5,102,345)	\$ (2,872,017)	\$ (8,530,148)	\$ (2,986,914)

See accompanying notes to consolidated financial statements.

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

	<b>For the Six Months Ended June 30,</b>	
	<b>2013</b>	<b>2012</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (8,511,704)	\$ (2,881,466)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation and amortization	159,735	75,262
Stock-based compensation expense	882,598	973,456
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable	(2,101,486)	(94,911)
Inventories	(27,741)	474
Prepaid expenses and other current assets	(262,963)	(74,953)
Deferred costs	(9,409)	(696,623)
Other assets	(11,844)	(27,318)
Accounts payable	2,316,452	(163,624)
Accrued expenses and other current liabilities	(132,324)	(132,069)
Deferred revenue	(1,001,353)	(3,081,797)
<b>Net cash used in operating activities</b>	<b>(8,700,039)</b>	<b>(6,103,569)</b>
<b>Cash flows from investing activities:</b>		
Purchases of equipment, molds, furniture and fixtures	(1,807,732)	(310,513)
Additions to patent rights	(89,778)	(141,294)
Proceeds from maturities of investment securities	3,000,000	6,000,000
Purchases of investment securities	(9,118,161)	(6,034,168)
<b>Net cash used in investing activities</b>	<b>(8,015,671)</b>	<b>(485,975)</b>
<b>Cash flows from financing activities:</b>		
Proceeds from exercise of stock options and warrants	645,655	5,267,093
Taxes paid related to net share settlement of equity awards	(104,329)	(28,916)
<b>Net cash provided by financing activities</b>	<b>541,326</b>	<b>5,238,177</b>
Effect of exchange rate changes on cash and cash equivalents	(7,708)	(33,427)
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>(16,182,092)</b>	<b>(1,384,794)</b>
<b>Cash and cash equivalents:</b>		
Beginning of period	52,097,064	19,357,932
End of period	\$ 35,914,972	\$ 17,973,138

See accompanying notes to consolidated financial statements.



**Table of Contents**

**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 and topical gel-based products. The Company has numerous partnerships with pharmaceutical companies as well as multiple internal product development programs.

The Company has developed both subcutaneous and intramuscular injection technology systems which include Vibex® disposable pressure-assisted auto injectors, Vision® reusable needle-free injectors, and disposable multi-use pen injectors. 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 Tj® injector system to administer their 5mg Tev-Tropin® brand hGH marketed in the U.S. The Company's needle-free injection device is marketed by Ferring with their 4mg and 10mg hGH formulations as Zomajet® 2 Vision and Zomajet® Vision X, respectively, in Europe and Asia. The Company has also licensed both disposable auto and pen injection devices to Teva for use in certain fields and territories and is engaged in product development activities for Teva utilizing these devices.

In addition to development of products with partners, the Company is developing its own drug/device combination products. The Company's lead product candidate, OTREXUP®, is a proprietary combination product comprised of a pre-filled methotrexate syringe and the Company's Medi-Jet® self-injection system for the potential treatment of moderate to severe rheumatoid arthritis (RA) and psoriasis. On December 17, 2012 the Company announced submission of a New Drug Application (NDA) for OTREXUP® and then on February 27, 2013 announced the FDA acceptance of that filing for review. The Prescription Drug User Fee Act (PDUFA) goal date for FDA approval is October 14, 2013. The Company has worldwide marketing rights for OTREXUP® and has provided Uman Pharma an exclusive license to commercialize the product in Canada. The Company's strategy is to potentially commercialize OTREXUP® in the U.S. on its own and to enter into licensing or distribution agreements for commercialization outside the U.S. The Company is also developing Vibex® QST for testosterone replacement therapy for men suffering from symptomatic testosterone deficiency and has conducted a pre-IND meeting with the FDA as part of preparing to initiate clinical development for this product.

In the gel-based product area, the Company announced with Actavis (formerly Watson Pharmaceuticals) on April 26, 2012, the launch of Gelnique 3%, the Company's topical oxybutynin gel product for the treatment of overactive bladder (OAB). The Company has a licensing agreement with Actavis under which Actavis is currently marketing Gelnique 3% in the U.S. In January 2012, the Company entered into a licensing agreement with Daewoong Pharmaceuticals under which Daewoong will commercialize this product, once approved in South Korea. The Company's gel portfolio also includes Elestrin® (estradiol gel) currently marketed by Meda Pharma in the U.S. for the treatment of moderate-to-severe vasomotor symptoms associated with menopause.

The Company has two facilities in the U.S. The Parenteral Products Group located in Minneapolis, Minnesota directs the manufacturing and marketing of the Company's reusable needle-free injection devices and related disposables, and develops its disposable pressure-assisted auto injector and pen injector systems. The Company's corporate head office and Product Development and Commercial Groups are located in Ewing, New Jersey, where the Company's gel based products were developed and where the Product Development and Commercial Groups direct the clinical, regulatory and commercial development of the Company's internal drug/device combination products.

**2. Basis of Presentation**

The accompanying unaudited consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America for interim financial information and with the instructions to Form 10-Q and Article 10 of the Securities and Exchange Commission's



**Table of Contents**

Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. The accompanying consolidated financial statements and notes should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended December 31, 2012. Operating results for the six months ended June 30, 2013 are not necessarily indicative of the results that may be expected for the year ending December 31, 2013.

*Investments*

All short-term and long-term investments are U.S. Treasury bills or U.S. Treasury notes that are classified as held-to-maturity because the Company has the positive intent and ability to hold the securities to maturity. The securities are carried at their amortized cost. The fair value of all securities is determined by quoted market prices. All long-term investments mature in less than two years. At June 30, 2013 the short-term investments had a fair value of \$33,105,024 and a carrying value of \$33,099,847 and the long-term investments had a fair value of \$6,010,890 and a carrying value of \$6,009,232. At December 31, 2012 the short-term investments had a fair value of \$21,116,952 and a carrying value of \$21,112,623 and the long-term investments had a fair value of \$12,016,530 and a carrying value of \$12,015,906.

**3. Stockholders Equity***Stock Options and Warrants*

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

The Company's 2008 Equity Compensation Plan (the Plan) allows for the grants of options, restricted stock, stock units, stock appreciation rights and/or performance awards to officers, directors, consultants and employees. Under the Plan, the maximum number of shares authorized for issuance is 15,000,000 and the maximum number of shares of stock that may be granted to any one participant during a calendar year is 1,000,000 shares. Options to purchase shares of common stock are granted at exercise prices not less than 100% of the fair market value on the dates of grant. The term of the options range from ten to eleven years and they vest in varying periods. As of June 30, 2013, the Plan had 222,669 shares available for grant. Stock option exercises are satisfied through the issuance of new shares.

A summary of stock option activity under the Plan as of June 30, 2013, and the changes during the six months then ended is as follows:

	Number of Shares	Wtd Avg Exercise Price (\$)	Wtd Avg Remaining Contractual Term (Years)	Aggregate Intrinsic Value (\$)
Outstanding at December 31, 2012	7,814,561	1.49		
Granted	836,880	3.96		
Exercised	(530,534)	0.72		1,736,879
Cancelled	(61,958)	3.73		
Outstanding at June 30, 2013	8,058,949	1.78	6.6	19,180,999
Exercisable at June 30, 2013	6,137,621	1.30	5.8	17,556,184

Total recognized compensation expense for stock options was approximately \$581,000 and \$504,000 for the first six months of 2013 and 2012, respectively, and was approximately \$321,000 and \$266,000 for the three month periods ended June 30, 2013 and 2012, respectively. As of June 30, 2013, there was approximately \$2,939,600 of total unrecognized compensation cost related to nonvested outstanding stock options that is expected to be recognized over a weighted average period of approximately 2.2 years.

**Table of Contents**

The per share weighted average fair value of options granted during the first six months of 2013 and 2012 were estimated as \$2.24 and \$1.49 on the date of grant using the Black-Scholes option pricing model based on the assumptions noted in the table below. Expected volatilities are based on the historical volatility of the Company's stock price. The weighted average expected life is based on both historical and anticipated employee behavior.

	June 30,	
	2013	2012
Risk-free interest rate	0.7%	0.7%
Annualized volatility	62.5%	61.0%
Weighted average expected life, in years	6.0	5.0
Expected dividend yield	0.0%	0.0%

*Stock Awards*

The employment agreements with certain members of executive management included stock-based incentives under which the executives could be awarded shares of common stock upon the occurrence of various triggering events. There were no shares awarded under these agreements in the first six months of 2013 and 35,000 shares awarded in the first six months of 2012.

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. Discretionary grants of common stock totaled 5,000 and 60,000 in the first six months of 2013 and 2012, respectively. The weighted average fair value of the shares granted was \$3.96 and \$2.59 in the first six months of 2013 and 2012, respectively.

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. Expense recognized in connection with performance and discretionary stock awards was approximately \$9,400 and \$275,000 in the first six months of 2013 and 2012, respectively, and was \$700 and \$13,000 in the three month periods ended June 30, 2013 and 2012, respectively.

A portion of the discretionary stock grants vested in the first six months of 2013 and 2012. Some of these grants 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 30,153 and 11,165 in 2013 and 2012, 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 \$104,329 and \$28,916 in 2013 and 2012, 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.

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 for stock-based compensation to directors was \$266,000 and \$194,400 in the six month periods ended June 30, 2013 and 2012, respectively, and was \$83,000 and \$182,800 in the three month periods ended June 30, 2013 and 2012, respectively.

As of June 30, 2013, a total of 5,000 shares previously granted as performance or discretionary awards were unvested and 194,446 shares granted to directors were unvested. As of June 30, 2013, there was approximately \$706,000 of total unrecognized compensation cost related to nonvested stock awards that is expected to be recognized over a weighted average period of approximately 11 months. The weighted average fair value of the shares granted in the first six months of 2013 and 2012 was \$3.96 and \$2.84 per share, respectively.

**Table of Contents***Long Term Incentive Program*

The Company's Board of Directors has approved a long term incentive program for the benefit of the Company's senior executives. Pursuant to the long term incentive program, the Company's senior executives have been awarded stock options and performance stock units with a value targeted at the median level of the Company's peer group. In 2013, the program was modified such that the value of the annual award for each senior executive was delivered one-third in the form of performance stock units, one-third in the form of shares of restricted stock and one-third in the form of stock options. In prior years, two thirds of the value for each senior executive was delivered in the form of stock options and one third of the value was delivered in the form of performance stock units. The stock options have a ten-year term, have an exercise price equal to the closing price of the Company's common stock on the date of grant, vest in quarterly installments over three years, and were otherwise granted on the same standard terms and conditions as other stock options granted pursuant to the Plan. The restricted stock vests in three equal annual installments. 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. No expense has been recognized in connection with the performance stock unit awards as the defined performance goals are not yet considered probable of achievement. The performance stock unit awards, restricted stock and stock options granted under the long term incentive program are summarized in the following table:

Grant Date	Performance Stock Units		Restricted Stock		Stock Options	
	Number of Shares	Fair Value on Grant Date	Number of Shares	Fair Value on Grant Date	Number of Options	Exercise Price
May 17, 2011	182,000	\$ 1.66			317,000	\$ 1.66
May 17, 2012					470,000	\$ 2.94
July 6, 2012	137,715	\$ 4.26			178,731	\$ 4.26
May 22, 2013	185,185	\$ 3.96	185,185	\$ 3.96	327,381	\$ 3.96

*Warrants*

In the first six months of 2013, 234,541 warrants were exercised resulting in proceeds to the Company of \$261,799. In the first six months of 2012, 2,585,510 warrants were exercised resulting in proceeds to the Company of \$5,171,020. Warrants to purchase a total of 2,781,428 shares of common stock were outstanding at June 30, 2013. The weighted average exercise price of the outstanding warrants was \$2.05.

**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 10,840,377 and 15,597,160 at June 30, 2013 and 2012, respectively. The table below discloses the basic and diluted loss per common share.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Net loss	\$ (5,103,256)	\$ (2,807,072)	\$ (8,511,704)	\$ (2,881,466)
Basic and diluted wtd avg common shares outstanding	126,462,677	104,551,742	126,285,677	104,105,156
Basic and diluted net loss per common share	\$ (0.04)	\$ (0.03)	\$ (0.07)	\$ (0.03)

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

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

Revenues by customer location are summarized as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
United States of America	\$ 5,145,676	\$ 2,991,985	\$ 8,672,963	\$ 8,202,153
Europe	604,268	1,489,520	1,537,907	2,660,753
Other	87,600	42,437	154,896	525,578
	\$ 5,837,544	\$ 4,523,942	\$ 10,365,766	\$ 11,388,484

Revenues by product type:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Injection devices and supplies	\$ 5,346,220	\$ 3,320,607	\$ 8,782,720	\$ 5,904,944
Transdermal products	491,324	1,203,335	1,583,046	5,483,540

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Teva	\$ 4,736,762	\$ 1,795,057	\$ 7,192,028	\$ 3,168,485
Ferring	529,943	1,489,520	1,463,582	2,660,753
Actavis (Watson)	224,788	1,025,976	1,099,116	4,687,855

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

In January 2012, the Company entered into a licensing agreement with Daewoong Pharmaceuticals ( Daewoong ) under which Daewoong will commercialize the Company's oxybutynin gel 3% product, once approved in South Korea. The agreement terms include an upfront payment, development and sales-based milestone payments and escalating royalties based on product sales in South Korea. Because the Company has no development responsibilities, the upfront and each milestone payment will be recognized as revenue when received. Royalties will be recognized as revenue when earned. The term of the agreement ends on the later of fifteen years following launch of the product or the expiration date of the last to expire patent. The Company recognized revenue of \$442,859 in the three months ended March 31, 2012 in connection with upfront and milestone payments.

*Pfizer License Agreement*

In December 2011, the Company licensed to Pfizer Inc.'s Consumer Healthcare Business Unit one of its drug delivery technologies to develop an undisclosed product on an exclusive basis for North America. Pfizer assumed full cost and responsibility for all clinical development, manufacturing, and commercialization of the product in the licensed territory, which also includes certain non-exclusive territories outside of North America. The Company received an upfront payment, and will receive development milestones and sales based milestones, as well as royalties on net sales for three years post



**Table of Contents**

launch in the U.S. Because the Company has no development responsibilities, the upfront and each milestone payment will be recognized as revenue when received. Royalties will be recognized as revenue when earned. The Company recognized revenue of \$750,000 in the third quarter of 2012, which was earned when Pfizer achieved a development milestone related to this undisclosed Consumer Healthcare product.

*Actavis License and Commercialization Agreement*

In July 2011, the Company entered into an exclusive licensing agreement with Actavis to commercialize, in the U.S. and Canada, the Company's topical oxybutynin gel 3% product, which was subsequently approved by the FDA in December 2011.

Under this agreement the Company received payments for certain manufacturing start-up activities and delivery of launch quantities, and has received and is entitled to receive future royalties on both the Company's oxybutynin gel 3% product and Actavis' oxybutynin gel product Gelnique® 10%, and will potentially receive sales based milestone payments. The milestone payment based on the achievement of regulatory approval was subject to reimbursement to Actavis if launch quantities were not delivered within a certain defined time period. The term of the agreement ends on the later of April 2024 or the expiration date of the last to expire patent.

The Company received a milestone payment from Actavis in December 2011 upon FDA approval, which was recorded as deferred revenue. This milestone payment was recognized as revenue in March of 2012, as launch quantities were delivered within the defined time period and the potential reimbursement liability was eliminated. In the six months ended June 30, 2012, the Company recognized revenue of \$4,687,855 in connection with product sales, development activities, and the milestone payment. In the six months ended June 30, 2013, the Company recognized revenue of \$1,099,116 in connection with product sales and royalties. Product sales to Actavis ended in the first quarter of 2013, as Actavis assumed all manufacturing of Gelnique 3% in 2013 as contracted.



**Table of Contents**

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

**Forward-Looking Statements**

Management's discussion and analysis of the significant changes in the consolidated results of operations, financial condition and cash flows of the Company is set forth below. Certain statements in this report may be considered to be forward-looking statements as that term is defined in the U.S. Private Securities Litigation Reform Act of 1995, such as statements that include the words expect, estimate, project, anticipate, should, intend, probability, risk, target, objective and other words and terms of similar meaning in connection with any discussion of, among other things, future operating or financial performance, strategic initiatives and business strategies, regulatory or competitive environments, our intellectual property and product development. In particular, these forward-looking statements include, among others, statements about:

our expectations regarding product development and commercialization of OTREXUP (Vibex MTX);

our expectations regarding product development of Vibex QS T;

our expectations regarding continued product development with Teva;

our plans regarding potential manufacturing and marketing partners;

our expectations regarding increases in our sales and marketing expenses in the last half of 2013;

our future cash flow and projected license, royalty and milestone revenue;

the impact of new accounting pronouncements; and

our expectations regarding the year ending December 31, 2013.

The words may, will, expect, intend, anticipate, estimate, believe, continue, and similar expressions may identify forward-looking statements but the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements involve known and unknown risks, uncertainties and achievements, and other factors that may cause our or our industry's actual results, levels of activity, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements. While we believe that we have a reasonable basis for each forward-looking statement contained in this report, we caution you that these statements are based on a combination of facts and factors currently known by us and projections of the future about which we cannot be certain. Many factors may affect our ability to achieve our objectives, including:

delays in product introduction and marketing or interruptions in supply;

a decrease in business from our major customers and partners;

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

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

our inability to effectively market our services or obtain and maintain arrangements with our customers, partners and manufacturers;

our inability to attract and retain key personnel;

adverse economic and political conditions; and

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

In addition, you should refer to the Risk Factors section of our Annual Report on Form 10-K for the year ended December 31, 2012 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.

---

## Table of Contents

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. is an emerging specialty pharmaceutical company that focuses on developing and commercializing self-administered parenteral pharmaceutical products and technologies and topical gel-based products. 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, Vision reusable needle-free injectors, and disposable multi-use pen injectors. 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<sup>®</sup> injector system to administer their 5mg Tev-Tropin<sup>®</sup> 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<sup>®</sup> 2 Vision and Zomajet<sup>®</sup> 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. Product sales in the first half of 2013 included shipments of commercial-ready Vibex auto-injector devices to Teva.

In addition to development of products with partners, we are developing our own drug/device combination products. Our lead product candidate, OTREXUP , is a proprietary combination product comprised of a pre-filled methotrexate syringe and our Medi-Jet self-injection system for the potential treatment of moderate to severe rheumatoid arthritis ( RA ) and psoriasis. On December 17, 2012 we announced submission of a New Drug Application ( NDA ) for OTREXUP and then on February 27, 2013 announced the FDA acceptance of that filing for review. The Prescription Drug User Fee Act ( PDUFA ) goal date for FDA approval is October 14, 2013. We have worldwide marketing rights for OTREXUP and have provided Uman Pharma an exclusive license to commercialize the product in Canada. Our strategy is to potentially commercialize OTREXUP in the U.S. on our own and to enter into licensing or distribution agreements for commercialization outside the U.S. We are also developing Vibex QS T for testosterone replacement therapy for men suffering from symptomatic testosterone deficiency and have conducted a pre-IND meeting with the FDA as part of preparing to initiate clinical development for this product.

In the gel-based product area, we announced with Actavis (formerly Watson Pharmaceuticals) on April 26, 2012, the launch of Gelnique 3% , our topical oxybutynin gel product for the treatment of overactive bladder ( OAB ). We have a licensing agreement with Actavis under which Actavis is currently marketing Gelnique 3% in the U.S. In January 2012, we entered into a licensing agreement with Daewoong Pharmaceuticals under which Daewoong will commercialize this product, once approved in South Korea. Our gel portfolio also includes Elestrin<sup>®</sup> (estradiol gel) currently marketed by Meda Pharma in the U.S. for the treatment of moderate-to-severe vasomotor symptoms associated with menopause.

We have two facilities in the U.S. The Parenteral Products Group located in Minneapolis, Minnesota directs the manufacturing and marketing of our reusable needle-free injection devices and related disposables, and develops our disposable pressure-assisted auto injector and pen injector systems. Our corporate head office and Product Development and Commercial Groups are located in Ewing, New Jersey, where our gel based products were developed and where the Product Development and Commercial Groups direct the clinical, regulatory and commercial development of our internal drug/device combination products.

**Table of Contents**

We have reported a net loss of \$8,511,704 for the six months ended June 30, 2013. Operating results for the six months ended June 30, 2013 are not necessarily indicative of the results that may be expected for the year ending December 31, 2013.

**Results of Operations***Three and Six Months Ended June 30, 2013 and 2012**Revenues*

Total revenues for the three and six-month periods ended June 30, 2013 were \$5,837,544 and \$10,365,766, respectively, compared to revenues for the same prior-year periods of \$4,523,942 and \$11,388,484, respectively. Product sales were \$4,512,891 and \$7,005,367 in the three and six-month periods ended June 30, 2013, respectively, compared to \$3,211,955 and \$5,706,065, in the three and six-month periods ended June 30, 2012, respectively. Product sales in the three and six-month periods ended June 30, 2013 included \$3,560,000 and \$4,126,000, respectively, of initial sales to Teva of pre-launch quantities of our Vibex<sup>®</sup> auto injector for Teva's generic epinephrine auto injector product. Product sales in the first half of 2013 and 2012 included \$509,869 and \$996,220, respectively, of sales of our topical oxybutynin gel 3% product to Actavis in connection with their marketing of Gelnique 3%, which was launched in April 2012. Product sales to Actavis ended in the first quarter of 2013, as Actavis assumed all manufacturing of Gelnique 3% in 2013 as contracted. Product revenue in the first half of 2013 also included approximately \$300,000 of revenue that had previously been deferred. The balance of our product sales in each period were primarily sales of reusable needle-free injector devices and disposable components. Our sales of needle-free injector related products are generated primarily from sales to Ferring and Teva. Ferring uses our needle-free injector with their 4mg and 10mg hGH formulations marketed as Zomajet<sup>®</sup> 2 Vision and Zomajet<sup>®</sup> Vision X, respectively, in Europe and Asia. Teva uses our needle-free injector with the Tjet<sup>®</sup> injector system to administer their 5mg Tev-Tropin<sup>®</sup> brand hGH marketed in the U.S. Sales to both Ferring and Teva decreased in the three and six-month periods ended June 30, 2013 compared to the same periods of 2012. Sales of the hGH drug product for both Ferring and Teva continue to grow, but we do not control our partners' inventory levels of our hGH injectors or disposable components and this can cause significant fluctuations in product sales.

Development revenue was \$588,164 and \$1,381,874 in the three and six-month periods ended June 30, 2013, respectively, compared to \$737,409 and \$3,723,485 in the same periods of the prior year. The revenue in the three and six-month periods ended June 30, 2013 was primarily due to auto injector and pen injector development work for Teva. The revenue in the first half of 2012 was primarily due to a non-recurring FDA approval milestone payment of \$2,500,000 recognized in connection with our license agreement with Actavis (Watson).

Licensing revenue was \$68,662 and \$138,007 in the three and six-month periods ended June 30, 2013, respectively, compared to \$109,093 and \$734,912 in the same periods of 2012. The licensing revenue in the second quarter and first six months of 2013 was primarily due to recognition of revenue deferred in prior years under agreements with Ferring. The licensing revenue in the first six months of 2012 was primarily due to an upfront license fee received in connection with our licensing agreement with Daewoong signed in January of 2012, along with license revenue recognized in connection with our license agreement with Actavis.

Royalty revenue was \$667,827 and \$1,840,518 in the three and six-month periods ended June 30, 2013, respectively, compared to \$465,485 and \$1,224,022 in the same prior-year periods. We receive royalties from Teva and Ferring related to needle-free injector device sales and/or hGH sales, from Actavis on sales of Gelnique, and from Meda Pharma on sales of Elestrin<sup>®</sup>. The primary reason for the increase in royalty revenue in 2013 compared to 2012 was that royalties were received from Actavis on sales of Gelnique in the first half of 2013, while no royalties were received in the first half of 2012 as Gelnique 3% was launched in April 2012.

*Cost of Revenues and Gross Profit*

For the three and six-month periods ended June 30, 2013, cost of product sales was \$3,182,767 and \$4,610,408, respectively, compared to \$2,028,530 and \$3,397,158 for the same periods of the prior year. Product gross margins were 29% and 37% in three-month periods ended June 30, 2013 and 2012, respectively, and were 34% and 40% for the six-month periods ended June 30, 2013 and 2012, respectively. In the second quarter and first half of 2013,

---

## **Table of Contents**

product gross margin decreased primarily due to a significant increase in sales to Teva of our Vibex auto injectors for epinephrine. We anticipate that the gross margin for this product will be slightly lower than for our needle-free injector products, as we will receive a higher royalty on end sales of epinephrine than the royalty received for hGH. Additionally, the gross margin in this quarter was impacted by additional quality release testing costs in connection with the initial large scale production runs. Finally, we have increased our manufacturing overhead expenses in anticipation of increased production activity in 2013 related to Vibex auto injectors for epinephrine and OTREXUP. Product gross margin in the first half of 2013 was favorably impacted by the recognition of previously deferred product revenue of approximately \$300,000 which had no related costs.

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 \$297,915 and \$897,417 for the three and six-month periods ended June 30, 2013, respectively, compared to \$502,581 and \$1,124,784 for the same prior-year periods. In the first six months of 2013, the development costs were primarily related to revenue recognized in connection with auto injector and pen injector development programs with Teva. In the first six months of 2012, development costs were related to auto injector and pen injector development work for Teva and certain manufacturing readiness activities under the Actavis license agreement.

### *Research and Development*

The majority of research and development expenses consist of external costs for studies and analysis activities, design work and prototype development. Research and development expenses were \$4,395,528 and \$7,468,213 in the three and six-month periods ended June 30, 2013, respectively, compared to \$2,482,785 and \$5,359,947 in the same periods of the prior year. In the first six months of 2013, expenses related to development of our Vibex QS T for testosterone replacement therapy increased by approximately \$1,316,000 to \$1,477,000 and personnel costs increased by approximately \$1,000,000 to \$3,045,000 due to employee additions. Expenses related to development of our OTREXUP auto injector product for delivery of methotrexate for the treatment of rheumatoid arthritis decreased by approximately \$783,000 to \$1,640,000 in the first six months of 2013 compared to 2012 due to a clinical study in process in the first half of 2012 that was completed later in the year.

### *Sales and Marketing*

Sales and marketing expenses totaled \$1,158,236 and \$2,039,489 for the three and six-month periods ended June 30, 2013, respectively, compared to \$187,594 and \$290,886 in the same prior-year periods. The increase in the first six months of 2013 compared to the first six months of 2012 was primarily due to expenses of approximately \$1,256,000 related to OTREXUP market research, product branding and pre-commercialization activities, and an increase of approximately \$417,000 in employee related expenses due to sales and marketing personnel added after the first half of 2012. We expect sales and marketing expenses to increase significantly in the last six months of 2013, primarily in connection with OTREXUP marketing and pre-commercialization activities which we anticipate could reach \$6.0 million for the year.

### *Business Development*

Business development expenses totaled \$188,049 and \$344,715 for the six months ended June 30, 2013 and 2012, respectively, compared to \$231,933 and \$564,708 in the same prior-year periods. The decrease for the first half of the year was primarily due to a decrease in legal expenses of approximately \$60,000 and a decrease in stock compensation expense of \$90,000 related to a one time stock grant in 2012.

### *General and Administrative*

General and administrative expenses totaled \$1,745,719 and \$3,539,483 in the three and six-month periods ended June 30, 2013, respectively, compared to \$1,881,056 and \$3,538,597 in the same periods of the prior year. The decrease in the quarter was mainly due to a decrease in professional fees of approximately \$200,000, partially offset by increases in patent related expenses of approximately \$40,000 and business insurance of \$20,000. In the first six months of 2013, employee and director compensation expenses, including noncash stock compensation expense, increased by approximately \$180,000 and patent related expenses increased by approximately \$150,000, while professional fees decreased by approximately \$300,000 and business insurance decreased by approximately \$100,000 due to a one time insurance refund.

**Table of Contents****Liquidity and Capital Resources**

At June 30, 2013, our cash and investments totaled \$75,024,051, which consisted of cash and cash equivalents of \$35,914,972, short-term investments of \$33,099,847, and long-term investments of \$6,009,232. All investments are U.S. Treasury bills or U.S. Treasury notes which we intend to hold to maturity. In the fourth quarter of 2012, we sold 14,259,868 shares of common stock at a price of \$4.00 per share in a public offering. The sales of common stock resulted in net proceeds of \$53,328,188 after deducting offering expenses of \$3,711,284. Proceeds from this offering are being used for further development of OTREXUP (our proprietary MTX Medi-Jet injection system for the treatment of rheumatoid arthritis), development of the Company's proprietary VIBEX QS T product for male testosterone deficiency and general corporate purposes. 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, marketing and business development activities. Net cash used in operating activities was \$8,700,039 and \$6,103,569 for the six months ended June 30, 2013 and 2012, respectively. The increase in cash used was driven primarily by an increase in net loss to \$8,511,704 for the first six months of 2013 from \$2,881,466 for the first six months of 2012. In the first six months of 2013, both accounts payable and accounts receivable increased by over \$2.0 million in connection with production and sales of pre-launch quantities of our Vibex auto injector for Teva's generic epinephrine auto injector product. In the first six months of 2012, cash used in operating activities was significantly impacted by a decrease in deferred revenue of approximately \$3.1 million related mainly to recognition of revenue previously deferred in connection with a non-recurring FDA approval milestone payment of \$2,500,000 received under our license agreement with Actavis.

*Net Cash Used in Investing Activities*

Net cash used in investing activities was \$8,015,671 in the first six months of 2013 compared to \$485,975 in the first six months of 2012. Cash used for purchases of equipment, molds, furniture and fixtures increased to \$1,807,732 in 2013 compared to \$310,513 in 2012, primarily related to OTREXUP commercial molds and assembly equipment. Additions to patent rights were \$89,778 in 2013 compared to \$141,294 in 2012. In the first six months of 2013 we used cash of \$9,118,161 to purchase investment securities and received proceeds of \$3,000,000 from the maturities of investment securities. In the first six months of 2012 we used cash of \$6,034,168 to purchase investment securities and received proceeds of \$6,000,000 from the maturities 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 Financing Activities*

Net cash provided by financing activities in the first six months of 2013 and 2012 was \$541,326 and \$5,238,177, respectively. In the first six months of 2013 we received proceeds of \$261,799 and \$383,856 from the exercise of 234,541 warrants and 530,534 options, respectively. In the first six months of 2012 we received proceeds of \$5,171,020 and \$96,073 from the exercise of 2,585,510 warrants and 82,153 options, respectively. In the first six months of 2013 and 2012, total payments for employees' income and employment tax obligations related to net share settlement of equity awards was \$104,329 and \$28,916, respectively.

---

## **Table of Contents**

### **Research and Development Programs**

Our current research and development activities are primarily related to OTREXUP (Vibex MTX), Vibex QS T and device development projects.

**OTREXUP (Vibex MTX).** In December 2012, we submitted a New Drug Application to the FDA for OTREXUP , a combination product for the delivery of methotrexate (MTX) using Medi-Jet technology, which NDA was accepted for filing on February 26, 2013. OTREXUP is being developed for subcutaneous administration of MTX to enhance the treatment of rheumatoid arthritis (RA), poly-articular-course juvenile RA and psoriasis.

In November 2012, we announced positive results from an open-label, randomized, crossover study comparing the systemic availability of OTREXUP to oral methotrexate in adult patients with rheumatoid arthritis. This study was designed to compare the relative systemic availability of methotrexate following oral administration to subcutaneous (SC) self-administered methotrexate using the Medi-Jet device. Patients were assigned to one of four dose levels of methotrexate, 10 mg, 15 mg, 20 mg, and 25 mg. Results showed that the systemic availability of methotrexate following oral dosing plateaus above 15 mg. Following administration of methotrexate with Medi-Jet , the systemic availability increased proportionally at every dose, which will extend the range of exposure compared to patients receiving oral therapy.

In September 2012, we announced positive results from an actual human use study in 101 RA patients. The results of this study showed that self-administration of MTX using the Vibex MTX (Medi-Jet ) is safe and well tolerated. Following standardized training by site personnel and review of written instructions, all 101 patients performed the self-administration successfully. In addition, the Medi-Jet device functioned correctly and as intended for each and every administration thereby demonstrating reliability and robustness. Results of the Ease of Use Questionnaire indicated that 98% of patients found the Medi-Jet device easy to use and 100% of patients found the instructions and training to be clear and easy to follow.

In June 2012, we announced positive results from a human factors usability study for our Medi-Jet methotrexate injection system. Fifty individuals representing three user groups participated in this study, including 17 RA patients, 16 lay caregivers and 17 healthcare professionals.

In August 2011, we announced positive results from a clinical PK study initiated in the first quarter of 2011 evaluating OTREXUP . The clinical study evaluated several dose strengths of methotrexate delivered with our Medi-Jet versus conventional needle and syringe administration by a healthcare professional.

As of June 30, 2013, we have incurred external expenses of approximately \$11,800,000 in connection with our OTREXUP development program, of which approximately \$1,600,000 was incurred in 2013. We have also incurred costs for molds and assembly equipment of approximately \$4,200,000, of which \$1,600,000 was incurred in 2013, that has been capitalized and included in equipment, molds, furniture and fixtures at June 30, 2013. We anticipate total spending on this program for development and capital equipment could approach \$7,000,000 in 2013 and we expect sales and marketing expense in 2013 will be approximately \$6,000,000.

**Vibex QS T.** We are developing Vibex QS T for testosterone replacement therapy for men suffering from symptomatic testosterone deficiency and have incurred total external costs of approximately \$2,414,000 in connection with this program, of which approximately \$1,477,000 was recognized as expense in 2013. We anticipate spending on this program for development will increase to approximately \$3,000,000 in 2013.

**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

---

## **Table of Contents**

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 June 30, 2013, excluding costs related to OTREXUP and Vibex QS T, we have incurred total external costs of approximately \$13,200,000 in connection with research and development activities associated with our auto and pen injectors, of which approximately \$1,600,000 was incurred in 2013. Approximately \$10,400,000 of the total costs of \$13,200,000 was initially deferred, of which approximately \$9,650,000 has been recognized as cost of sales and \$750,000 remains deferred as of June 30, 2013. This remaining deferred balance will be recognized as cost of sales 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 2013, 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 OTREXUP project, 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 \$4,000,000 for the six months ended June 30, 2013.

### **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, 2012.

### *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 June 30, 2013 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.



**Table of Contents**

*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 are effective.

**Internal Control over Financial Reporting**

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

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

**Table of Contents****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, 2012, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K are not the only risks facing us. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

*Item 6. EXHIBITS*

## (a) Exhibit Index

Exhibit No.	Description
3.1	Certificate of Amendment to Certificate of Incorporation of Antares Pharma, Inc. (Filed as Exhibit 3.1 to Form 8-K on May 28, 2013 and incorporated herein by reference)
3.2	Certificate of Incorporation of Antares Pharma, Inc. (Filed as Exhibit 4.1 to the Company's Registration Statement on Form S-3 filed on April 12, 2006 and incorporated herein by reference)
3.3	Certificate of Amendment to Certificate of Incorporation of Antares Pharma, Inc. (Filed as Exhibit 3.1 to Form 8-K on May 19, 2008 and incorporated herein by reference)
3.4	Amended and Restated By-laws of Antares Pharma, Inc. (Filed as Exhibit 3.1 to Form 8-K on May 15, 2007 and incorporated herein by reference)
10.1+*	Form of Performance Stock Unit Grant
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

+ Indicates management contract or compensatory plan or arrangement.

\* Confidential portions of this document have been redacted and have been filed separately with the Securities and Exchange Commission.

# 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.**

August 7, 2013

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

August 7, 2013

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