ANTARES PHARMA, INC.
Form 10-Q
May 08, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D)

OF THE SECURITIES EXCHANGE ACT OF 1934.

For the quarterly period ended March 31, 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

(609) 359-3020

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨ (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 x

The number of shares outstanding of the registrant s Common Stock, $.01 par value, as of May 1, 2013 was 126,175,413.

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PART I FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

ANTARES PHARMA, INC.

CONSOLIDATED BALANCE SHEETS

	March 31, 2013 (Unaudited)	December 31, 2012
Assets		
Current Assets:		
Cash and cash equivalents	$ 38,126,055	$ 52,097,064
Short-term investments	30,154,988	21,112,623
Accounts receivable	1,729,232	2,228,650
Inventories	705,813	1,002,703
Deferred costs	895,562	755,159
Prepaid expenses and other current assets	688,908	463,033
Total current assets	72,300,558	77,659,232
Equipment, molds, furniture and fixtures, net	4,299,655	3,583,104
Patent rights, net	1,112,614	1,123,652
Goodwill	1,095,355	1,095,355
Long-term investments	12,013,415	12,015,906
Other assets	61,050	49,361
Total Assets	$ 90,882,647	$ 95,526,610
Liabilities and Stockholders Equity		
Current Liabilities:		
Accounts payable	$ 3,171,717	$ 2,864,507
Accrued expenses and other liabilities	1,758,710	2,916,700
Deferred revenue	1,466,020	2,157,016
Total current liabilities	6,396,447	7,938,223
Deferred revenue long term	913,395	1,037,795
Total liabilities	7,309,842	8,976,018
Stockholders Equity:		
Preferred Stock: $0.01 par, authorized 3,000,000 shares, none outstanding		
Common Stock: $0.01 par; authorized 150,000,000 shares; 126,170,879 and 125,949,024 issued and outstanding at March 31, 2013 and December 31, 2012, respectively	1,261,709	1,259,490
Additional paid-in capital	239,193,409	238,745,612
Accumulated deficit	(156,197,613)	(152,789,165)
Accumulated other comprehensive loss	(684,700)	(665,345)
	83,572,805	86,550,592

Total Liabilities and Stockholders Equity	$ 90,882,647	$ 95,526,610

See accompanying notes to consolidated financial statements.

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ANTARES PHARMA, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

	For the Three Months Ended March 31,	
	2013	**2012**
Revenue:		
Product sales	$ 2,492,476	$ 2,494,110
Development revenue	793,710	2,986,076
Licensing revenue	69,345	625,819
Royalties	1,172,691	758,537
Total revenue	4,528,222	6,864,542
Cost of revenue:		
Cost of product sales	1,427,641	1,368,628
Cost of development revenue	599,502	622,203
Total cost of revenue	2,027,143	1,990,831
Gross profit	2,501,079	4,873,711
Operating expenses:		
Research and development	3,072,685	2,877,162
Sales and marketing	881,253	103,292
Business development	156,666	332,775
General and administrative	1,793,764	1,657,541
Total operating expenses	5,904,368	4,970,770
Operating loss	(3,403,289)	(97,059)
Other income (expense)	(5,159)	22,665
Net loss	$ (3,408,448)	$ (74,394)
Basic and diluted net loss per common share	$ (0.03)	$ (0.00)
Basic and diluted weighted average common shares outstanding	126,106,713	103,658,571

See accompanying notes to consolidated financial statements.

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ANTARES PHARMA, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(UNAUDITED)

	For the Three Months Ended March 31,	
	2013	**2012**
Net loss	$ (3,408,448)	$ (74,394)
Foreign currency translation adjustment	(19,355)	(40,503)
Comprehensive loss	$ (3,427,803)	$ (114,897)

See accompanying notes to consolidated financial statements.

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ANTARES PHARMA, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	For the Three Months Ended March 31,	
	2013	**2012**
Cash flows from operating activities:		
Net loss	$ (3,408,448)	$ (74,394)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	74,618	46,246
Stock-based compensation expense	451,276	511,716
Changes in operating assets and liabilities:		
Accounts receivable	499,418	1,126,358
Inventories	294,873	(405,722)
Prepaid expenses and other current assets	(144,011)	118,747
Deferred costs	(147,108)	(529,366)
Other assets	(11,844)	(36,629)
Accounts payable	307,521	787,047
Accrued expenses and other current liabilities	(1,155,935)	(490,727)
Deferred revenue	(803,503)	(2,569,332)
Net cash used in operating activities	(4,043,143)	(1,516,056)
Cash flows from investing activities:		
Purchases of equipment, molds, furniture and fixtures	(763,600)	(205,345)
Additions to patent rights	(38,100)	(21,711)
Proceeds from maturities of investment securities		3,000,000
Purchases of investment securities	(9,118,161)	(3,008,366)
Net cash used in investing activities	(9,919,861)	(235,422)
Cash flows from financing activities:		
Proceeds from exercise of stock options and warrants	103,069	582,940
Taxes paid related to net share settlement of equity awards	(104,329)	(28,916)
Net cash provided by (used in) financing activities	(1,260)	554,024
Effect of exchange rate changes on cash and cash equivalents	(6,745)	7,107
Net decrease in cash and cash equivalents	(13,971,009)	(1,190,347)
Cash and cash equivalents:		
Beginning of period	52,097,064	19,357,932
End of period	$ 38,126,055	$ 18,167,585

See accompanying notes to consolidated financial statements.

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ANTARES PHARMA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

1. Description of Business

Antares Pharma, Inc. (the Company or Antares) is an emerging specialty pharmaceutical company that focuses on developing and commercializing self-administered parenteral pharmaceutical products and technologies 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 Tjet® injector system to administer their 5mg Tev-Tropin® brand hGH marketed in the U.S. The Company s needle-free injection device is marketed by Ferring with their 4mg and 10mg hGH formulations as Zomajet® 2 Vision and Zomajet® Vision X, respectively, in Europe and Asia. The Company has also licensed both disposable auto and pen injection devices to Teva for use in certain fields and territories and is engaged in product development activities for Teva utilizing these devices.

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 QS T 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 Actavis Pharmaceuticals) on April 26, 2012, the launch of Gelnique 3% , the Company s topical oxybutynin gel product for the treatment of overactive bladder (OAB), which was approved by the FDA in December 2011. 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

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and with the instructions to Form 10-Q and Article 10 of the Securities and Exchange Commission s Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. The accompanying consolidated financial statements and notes should be read in conjunction with the Company s Annual Report on Form 10-K for the year ended December 31, 2012. Operating results for the three months ended March 31, 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 March 31, 2013 the short-term investments had a fair value of $30,158,793 and a carrying value of $30,154,988 and the long-term investments had a fair value of $12,017,910 and a carrying value of $12,013,415. 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, Stock Awards and Warrants

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

The Company s 2008 Equity Compensation Plan (the Plan) allows for grants in the form of incentive stock options, nonqualified stock options, stock units, stock awards, stock appreciation rights, dividend equivalents and other stock-based awards. All of the Company s officers, direc