

ANTARES PHARMA, INC.

Form 10-Q

November 06, 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 September 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

(609) 359-3020

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

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

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

Large accelerated filer Accelerated filer
Non-accelerated filer (do not check if a smaller reporting company) Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

The number of shares outstanding of the registrant's Common Stock, \$.01 par value, as of November 6, 2013 was 127,613,404.

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

| | September 30, 2013 (Unaudited) | December 31, 2012 |
|---|---|------------------------------|
| Assets | | |
| Current Assets: | | |
| Cash and cash equivalents | \$ 42,960,486 | \$ 52,097,064 |
| Short-term investments | 27,053,333 | 21,112,623 |
| Accounts receivable, net | 3,405,395 | 2,228,650 |
| Inventories, net | 1,804,695 | 1,002,703 |
| Deferred costs | 317,514 | 755,159 |
| Prepaid expenses and other current assets | 1,001,195 | 463,033 |
| Total current assets | 76,542,618 | 77,659,232 |
| Equipment, molds, furniture and fixtures, net | 6,013,707 | 3,583,104 |
| Patent rights, net | 1,217,720 | 1,123,652 |
| Goodwill | 1,095,355 | 1,095,355 |
| Long-term investments | | 12,015,906 |
| Other assets | 61,241 | 49,361 |
| Total Assets | \$ 84,930,641 | \$ 95,526,610 |
| Liabilities and Stockholders Equity | | |
| Current Liabilities: | | |
| Accounts payable | \$ 4,689,615 | \$ 2,864,507 |
| Accrued expenses and other liabilities | 4,863,980 | 2,916,700 |
| Deferred revenue | 633,970 | 2,157,016 |
| Total current liabilities | 10,187,565 | 7,938,223 |
| Deferred revenue long term | 874,596 | 1,037,795 |
| Total liabilities | 11,062,161 | 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; 127,230,176 and 125,949,024 issued and outstanding at September 30, 2013 and December 31, 2012, respectively | 1,272,302 | 1,259,490 |
| Additional paid-in capital | 240,919,182 | 238,745,612 |

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| | | |
|--|----------------------|----------------------|
| Accumulated deficit | (167,660,826) | (152,789,165) |
| Accumulated other comprehensive loss | (662,178) | (665,345) |
| | 73,868,480 | 86,550,592 |
| Total Liabilities and Stockholders Equity | \$ 84,930,641 | \$ 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 September 30, | | For the Nine Months Ended September 30, | |
|--|---|----------------|--|----------------|
| | 2013 | 2012 | 2013 | 2012 |
| Revenue: | | | | |
| Product sales | \$ 3,047,091 | \$ 2,052,398 | \$ 10,052,458 | \$ 7,758,463 |
| Development revenue | 1,299,328 | 2,606,482 | 2,681,202 | 6,329,967 |
| Licensing revenue | 69,231 | 77,284 | 207,238 | 812,196 |
| Royalties | 1,092,174 | 949,753 | 2,932,692 | 2,173,775 |
| Total revenue | 5,507,824 | 5,685,917 | 15,873,590 | 17,074,401 |
| Cost of revenue: | | | | |
| Cost of product sales | 1,909,060 | 1,673,849 | 6,519,468 | 5,071,007 |
| Cost of development revenue | 1,095,542 | 1,622,640 | 1,992,959 | 2,747,424 |
| Total cost of revenue | 3,004,602 | 3,296,489 | 8,512,427 | 7,818,431 |
| Gross profit | 2,503,222 | 2,389,428 | 7,361,163 | 9,255,970 |
| Operating expenses: | | | | |
| Research and development | 4,318,011 | 3,900,475 | 11,786,224 | 9,260,422 |
| Sales and marketing | 2,576,247 | 237,067 | 4,615,736 | 527,953 |
| Business development | 142,017 | 219,953 | 486,732 | 784,661 |
| General and administrative | 1,836,127 | 1,551,147 | 5,375,610 | 5,089,744 |
| Total operating expenses | 8,872,402 | 5,908,642 | 22,264,302 | 15,662,780 |
| Operating loss | (6,369,180) | (3,519,214) | (14,903,139) | (6,406,810) |
| Other income (expense) | 9,223 | (15,025) | 31,478 | (8,895) |
| Net loss | \$ (6,359,957) | \$ (3,534,239) | \$ (14,871,661) | \$ (6,415,705) |
| Basic and diluted net loss per common share | \$ (0.05) | \$ (0.03) | \$ (0.12) | \$ (0.06) |
| Basic and diluted weighted average common shares outstanding | 127,162,064 | 108,961,792 | 126,581,018 | 105,735,855 |

See accompanying notes to consolidated financial statements.

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

| | For the Three Months | | For the Nine Months Ended | |
|---|-----------------------------|----------------|----------------------------------|----------------|
| | Ended | | September 30, | |
| | September 30, | | September 30, | |
| | 2013 | 2012 | 2013 | 2012 |
| Net loss | \$ (6,359,957) | \$ (3,534,239) | \$ (14,871,661) | \$ (6,415,705) |
| Foreign currency translation adjustment | 21,611 | 11,500 | 3,167 | (93,948) |
| Comprehensive loss | \$ (6,338,346) | \$ (3,522,739) | \$ (14,868,494) | \$ (6,509,653) |

See accompanying notes to consolidated financial statements.

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

| | For the Nine Months Ended September 30, | |
|--|--|--------------------|
| | 2013 | 2012 |
| Cash flows from operating activities: | | |
| Net loss | \$ (14,871,661) | \$ (6,415,705) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 288,188 | 178,030 |
| Stock-based compensation expense | 1,534,100 | 1,464,225 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (1,176,745) | 484,020 |
| Inventories | (804,009) | (2,736) |
| Prepaid expenses and other current assets | (349,833) | (663,796) |
| Deferred costs | 440,051 | 423,856 |
| Other assets | (11,844) | (27,322) |
| Accounts payable | 1,387,543 | 321,607 |
| Accrued expenses and other current liabilities | 1,946,548 | 404,423 |
| Deferred revenue | (1,676,365) | (4,143,463) |
| Net cash used in operating activities | (13,294,027) | (7,976,861) |
| Cash flows from investing activities: | | |
| Purchases of equipment, molds, furniture and fixtures | (2,184,568) | (2,425,454) |
| Additions to patent rights | (195,558) | (283,871) |
| Proceeds from maturities of investment securities | 15,000,000 | 9,000,000 |
| Purchases of investment securities | (9,118,161) | (15,077,176) |
| Net cash provided by (used in) investing activities | 3,501,713 | (8,786,501) |
| Cash flows from financing activities: | | |
| Proceeds from exercise of stock options and warrants | 756,611 | 9,601,723 |
| Taxes paid related to net share settlement of equity awards | (104,329) | (28,916) |
| Net cash provided by financing activities | 652,282 | 9,572,807 |
| Effect of exchange rate changes on cash and cash equivalents | 3,454 | (7,475) |
| Net decrease in cash and cash equivalents | (9,136,578) | (7,198,030) |
| Cash and cash equivalents: | | |
| Beginning of period | 52,097,064 | 19,357,932 |

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| | | | | |
|---|----|------------|----|------------|
| End of period | \$ | 42,960,486 | \$ | 12,159,902 |
| Noncash investing activities: | | | | |
| Purchases of equipment, molds, furniture and fixtures recorded in accounts payable and accrued expenses | \$ | 437,504 | \$ | 358,828 |

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. On October 14, 2013 the Company announced the approval of OTREXUP (methotrexate) injection by the U.S. Food and Drug Administration (FDA). OTREXUP is the first FDA approved subcutaneous methotrexate for once weekly self-administration with an easy-to-use, single dose, disposable auto injector. OTREXUP is indicated for adults with severe active rheumatoid arthritis or children with active polyarticular juvenile idiopathic arthritis and adults with severe recalcitrant psoriasis. 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 commercialize OTREXUP in the U.S. on its own and to enter into licensing or distribution agreements for commercialization outside the rheumatology area and outside the U.S. The Company is also developing Vibex® QuickShot (QST) for testosterone replacement therapy for men suffering from symptomatic testosterone deficiency and announced on September 16, 2013 that the first patients have been dosed in a clinical study evaluating testosterone administered weekly by subcutaneous injection via the Vibex® QST auto injector device. Up to 45 patients will be enrolled in the study at approximately eight investigative sites in the United States.

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 Elestri® (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.

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The accompanying unaudited consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America for interim financial information and with the instructions to Form 10-Q and Article 10 of the Securities and Exchange Commission's Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. The accompanying consolidated financial statements and notes should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended December 31, 2012. Operating results for the nine months ended September 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 September 30, 2013 the short-term investments had a fair value of \$27,070,089 and a carrying value of \$27,053,333. 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*

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 September 30, 2013, the Plan had 389,363 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 September 30, 2013, and the changes during the nine months then ended is as follows:

| Number of Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual | Aggregate Intrinsic Value (\$) |
|------------------------|--|---|--------------------------------------|
|------------------------|--|---|--------------------------------------|

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| | | (\$) | Term (Years) | |
|-----------------------------------|-----------|------|--------------|------------|
| Outstanding at December 31, 2012 | 7,814,561 | 1.49 | | |
| Granted | 904,380 | 4.01 | | |
| Exercised | (707,285) | 0.72 | | 2,379,554 |
| Cancelled | (197,276) | 3.49 | | |
| Outstanding at September 30, 2013 | 7,814,380 | 1.80 | 6.4 | 17,703,665 |
| Exercisable at September 30, 2013 | 6,234,160 | 1.38 | 5.7 | 16,696,929 |

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Total recognized compensation expense for stock options was approximately \$982,000 and \$799,000 for the first nine months of 2013 and 2012, respectively, and was approximately \$401,000 and \$295,000 for the three month periods ended September 30, 2013 and 2012, respectively. As of September 30, 2013, there was approximately \$2,517,935 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.

The per share weighted average fair value of options granted during the first nine months of 2013 and 2012 was estimated as \$2.27 and \$1.63 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.

| | September 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 include 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 nine months of 2013 and 35,000 shares were awarded in the first nine 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 60,000 in the first nine months of 2012 at a weighted average fair value of \$2.59.

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 \$8,700 and \$288,000 in the first nine months of 2013 and 2012, respectively, and was \$0 and \$13,000 in the three month periods ended September 30, 2013 and 2012, respectively.

A portion of the discretionary stock grants vested in the first nine 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 \$470,000 and \$377,200 in the nine month periods ended September 30, 2013 and 2012, respectively, and was \$204,000 and \$182,800 in the three month periods ended September 30, 2013 and 2012, respectively.

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As of September 30, 2013, a total of 212,618 shares granted to directors were unvested. As of September 30, 2013, there was approximately \$566,000 of total unrecognized compensation cost related to nonvested stock awards that is expected to be recognized over a weighted average period of approximately 8 months. The weighted average fair value of the shares granted in the first nine months of 2013 and 2012 was \$4.01 and \$3.25 per share, respectively.

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. Expense recognized in connection with the restricted stock in the three and nine-month periods ended September 30, 2013 was \$46,000 and \$73,000, respectively. 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 nine months of 2013, 234,541 warrants were exercised resulting in proceeds to the Company of \$261,799. In the first nine months of 2012, the Company received proceeds of \$8,962,270 from the exercise of 3,731,135 warrants. Warrants to purchase a total of 1,781,428 shares of common stock were outstanding at September 30, 2013, at a weighted average exercise price of \$1.08.

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 9,595,808 and 12,765,470 at September 30, 2013 and 2012, respectively. The table below discloses the basic and diluted loss per common share.

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| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|-------------------------------------|----------------|------------------------------------|----------------|
| | 2013 | 2012 | 2013 | 2012 |
| Net loss | \$ (6,359,957) | \$ (3,534,239) | \$ (14,871,661) | \$ (6,415,705) |
| Basic and diluted weighted average common shares outstanding | 127,162,064 | 108,961,792 | 126,581,018 | 105,735,855 |
| Basic and diluted net loss per common share | \$ (0.05) | \$ (0.03) | \$ (0.12) | \$ (0.06) |

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 September 30, | | Nine Months Ended September 30, | |
|--------------------------|-------------------------------------|--------------|------------------------------------|---------------|
| | 2013 | 2012 | 2013 | 2012 |
| United States of America | \$ 4,390,966 | \$ 4,881,106 | \$ 13,063,929 | \$ 13,083,259 |
| Europe | 1,047,748 | 787,368 | 2,585,655 | 3,448,121 |
| Other | 69,110 | 17,443 | 224,006 | 543,021 |
| | \$ 5,507,824 | \$ 5,685,917 | \$ 15,873,590 | \$ 17,074,401 |

Revenues by product type:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--------------------------------|-------------------------------------|--------------|------------------------------------|--------------|
| | 2013 | 2012 | 2013 | 2012 |
| Injection devices and supplies | \$ 5,100,253 | \$ 3,600,400 | \$ 13,882,973 | \$ 9,505,344 |
| Transdermal products | 407,571 | 2,085,517 | 1,990,617 | 7,569,057 |

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---------|-------------------------------------|--------------|------------------------------------|--------------|
| | 2013 | 2012 | 2013 | 2012 |
| Teva | \$ 4,004,531 | \$ 2,797,761 | \$ 11,196,559 | \$ 5,966,246 |
| Ferring | 1,047,750 | 783,757 | 2,511,332 | 3,444,510 |

| | | | | |
|------------------|---------|-----------|-----------|-----------|
| Actavis (Watson) | 202,813 | 1,171,633 | 1,301,929 | 5,859,488 |
|------------------|---------|-----------|-----------|-----------|

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 nine months ended September 30, 2012 in connection with upfront and milestone payments.

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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 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 nine months ended September 30, 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 nine months ended September 30, 2012, the Company recognized revenue of \$5,859,488 in connection with product sales, development activities, and the milestone payment. In the nine months ended September 30, 2013, the Company recognized revenue of \$1,301,929 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.

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

Forward-Looking Statements

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

our expectations regarding product development and commercialization of OTREXUP ;

our expectations regarding product development of Vibex[®] QST;

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

delays in product introduction and marketing or interruptions in supply;

a decrease in business from our major customers and partners;

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

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

our inability to 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.

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

Overview

Antares Pharma, Inc. 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[®] injector system to administer their 5mg Tev-Tropin[®] brand hGH marketed in the U.S. Our needle-free injection device is marketed by Ferring with their 4mg and 10mg hGH formulations as Zomajet[®] 2 Vision and Zomajet[®] Vision X, respectively, in Europe and Asia. We have also licensed both disposable auto and pen injection devices to Teva for use in certain fields and territories and are engaged in product development activities for Teva utilizing these devices. Sales in 2013 included shipments of 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 the Company's Medi-Jet self-injection system. On October 14, 2013 we announced the approval of OTREXUP[®] (methotrexate) injection by the U.S. Food and Drug Administration (FDA). OTREXUP[®] is the first FDA approved subcutaneous methotrexate for once weekly self-administration with an easy-to-use, single dose, disposable auto injector. OTREXUP[®] is indicated for adults with severe active rheumatoid arthritis or children with active polyarticular juvenile idiopathic arthritis and adults with severe recalcitrant psoriasis. 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 commercialize OTREXUP[®] in the U.S. on our own and to enter into licensing or distribution agreements for commercialization outside the rheumatology area and outside the U.S. We are also developing Vibex[®] QuickShot (QST) for testosterone replacement therapy for men suffering from symptomatic testosterone deficiency and announced on September 16, 2013 that the first patients have been dosed in a clinical study evaluating testosterone administered weekly by subcutaneous injection via the Vibex[®] QST auto injector device. Up to 45 patients will be enrolled in the study at approximately eight investigative sites in the United States.

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[®] (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.

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We have reported a net loss of \$14,871,661 for the nine months ended September 30, 2013. Operating results for the nine months ended September 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 Nine Months Ended September 30, 2013 and 2012**Revenues*

Total revenues for the three and nine-month periods ended September 30, 2013 were \$5,507,824 and \$15,873,590, respectively, compared to revenues for the same prior-year periods of \$5,685,917 and \$17,074,401, respectively. Product sales were \$3,047,091 and \$10,052,458 in the three and nine-month periods ended September 30, 2013, respectively, compared to \$2,052,398 and \$7,758,463, in the three and nine-month periods ended September 30, 2012, respectively. Product sales in the three and nine-month periods ended September 30, 2013 included \$2,078,000 and \$6,204,000, respectively, of initial sales to Teva of pre-launch quantities of our Vibex[®] auto injector for Teva's generic epinephrine auto injector product. Product sales for the nine-month periods ended September 30, 2013 and 2012 included \$509,869 and \$2,589,380, 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 nine months 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[®] 2 Vision and Zomajet[®] Vision X, respectively, in Europe and Asia. Teva uses our needle-free injector with the Tjet[®] injector system to administer their 5mg Tev-Tropin[®] brand hGH marketed in the U.S. Sales to Ferring increased in the three-month period ended September 30, 2013 compared to the same prior-year period, but sales to both Ferring and Teva decreased in the nine-month period ended September 30, 2013 compared to the same period 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 \$1,299,328 and \$2,681,202 in the three and nine-month periods ended September 30, 2013, respectively, compared to \$2,606,482 and \$6,329,967 in the same periods of the prior year. The development revenue in the three and nine-month periods ended September 30, 2013 was primarily due to auto injector and pen injector development work for Teva. The development revenue in the three months ended September 30, 2012 was primarily due to auto injector and pen injector development work for Teva, but also included a \$750,000 milestone payment from Pfizer. The development revenue in the first nine months of 2012 included a non-recurring FDA approval milestone payment of \$2,500,000 recognized in connection with our license agreement with Actavis (Watson), and included auto injector and pen injector development work for Teva and the Pfizer development milestone.

Licensing revenue was \$69,231 and \$207,238 in the three and nine-month periods ended September 30, 2013, respectively, compared to \$77,284 and \$812,196 in the same periods of 2012. The licensing revenue in the third quarter and first nine months of 2013 was primarily due to recognition of revenue deferred in prior years under agreements with Ferring. The licensing revenue in the first nine 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 \$1,092,174 and \$2,932,692 in the three and nine-month periods ended September 30, 2013, respectively, compared to \$949,753 and \$2,173,775 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®. The increase in royalty revenue in the first nine months of 2013 compared

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to 2012 was primarily the result of increases in royalties from Actavis and Teva. The increase in royalties from Actavis occurred because royalties were received in each of the first three quarters of 2013 while no royalties were received until the third quarter of 2012 as Gelnique 3% was launched in April 2012. The increase in royalties from Teva resulted from an increase in their net sales of hGH.

Cost of Revenues and Gross Profit

For the three and nine-month periods ended September 30, 2013, cost of product sales was \$1,909,060 and \$6,519,468, respectively, compared to \$1,673,849 and \$5,071,007 for the same periods of the prior year. Product gross margins were 37% and 18% in three-month periods ended September 30, 2013 and 2012, respectively, and were 35% in each of the nine-month periods ended September 30, 2013 and 2012. In the third quarter and first nine months of 2013, product gross margins were affected by a significant increase in sales to Teva of our Vibex[®] auto injectors for epinephrine. In 2013, product gross margins related to this product were lower than we expect in the future due to quality release testing costs in connection with initial large scale production runs that we do not expect to incur in the future. Gross margins in 2013 have also been affected by increased manufacturing overhead expenses in anticipation of increased production activity related to Vibex[®] auto injectors for epinephrine and OTREXUP[®]. Product gross margin in the first nine-months of 2013 was favorably impacted by the recognition of previously deferred product revenue of approximately \$300,000 which had no related costs. The gross margins in the three and nine-month periods of 2012 included the effect of sales of our topical oxybutynin gel 3% product to Watson at a lower gross profit than is realized on injector related product sales.

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 \$1,095,542 and \$1,992,959 for the three and nine-month periods ended September 30, 2013, respectively, compared to \$1,622,640 and \$2,747,424 for the same prior-year periods. In the first nine 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 nine 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 (R&D) expenses consist of external costs for studies and analysis activities, design work and prototype device development. R&D expenses were \$4,318,011 and \$11,786,224 in the three and nine-month periods ended September 30, 2013, respectively, compared to \$3,900,475 and \$9,260,422 in the same periods of the prior year. The increase in the third quarter of 2013 compared to 2012 was primarily due to increases in expenses related to development of our Vibex[®] QST for testosterone replacement therapy of approximately \$400,000 and payroll costs of approximately \$600,000, partially offset by a decrease in expenses related to development of our OTREXUP[®] auto injector product for delivery of methotrexate for the treatment of rheumatoid arthritis of approximately \$800,000. In the first nine months of 2013, expenses related to our Vibex[®] QST project increased by approximately \$1,712,000 to \$2,032,000 and payroll costs increased by approximately \$1,570,000 to \$4,725,000 due to employee additions. Expenses related to OTREXUP[®] development decreased by approximately \$1,614,000 to \$2,963,000 in the first nine months of 2013 compared to 2012 due to a clinical study in process in 2012. The remaining increase in R&D expenses in the first nine months of 2013 compared to 2012 consisted of an increase in other direct project costs of approximately \$300,000 and an increase in other indirect R&D expenses of approximately \$560,000.

Sales and Marketing

Sales and marketing expenses totaled \$2,576,247 and \$4,615,736 for the three and nine-month periods ended September 30, 2013, respectively, compared to \$237,067 and \$527,953 in the same prior-year periods. The increase in the first nine months of 2013 compared to the first nine months of 2012 was primarily due to expenses of approximately \$3,200,000 related to OTREXUP market research, product branding and pre-commercialization activities, and an increase of approximately \$800,000 in employee related expenses due to sales and marketing personnel added in the last 12 months. We expect sales and marketing expenses to continue to increase, primarily in connection with OTREXUP marketing and pre-commercialization activities which we anticipate could reach \$7.0 million for the year.

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Business Development

Business development expenses totaled \$142,017 and \$486,732 for the three and nine months ended September 30, 2013 and 2012, respectively, compared to \$219,953 and \$784,661 in the same prior-year periods. The decrease for the first nine months was primarily due to a decrease in legal expenses of approximately \$120,000 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 \$1,836,127 and \$5,375,610 in the three and nine-month periods ended September 30, 2013, respectively, compared to \$1,551,147 and \$5,089,744 in the same periods of the prior year. The increase in the quarter was mainly due to an increase in payroll related expenses. The increase in the first nine months of 2013 compared to 2012 was mainly due to an increase in payroll related and patent expenses of approximately \$600,000 and \$130,000, respectively. These increases were partially offset by reductions primarily in professional fees of \$350,000 and a one-time insurance refund of approximately \$100,000.

Liquidity and Capital Resources

At September 30, 2013, our cash and investments totaled \$70,013,819, which consisted of cash and cash equivalents of \$42,960,486, and short-term investments of \$27,053,333. 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 development and commercialization of OTREXUP[®], development of the Company's proprietary VIBEXQST 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 \$13,294,027 and \$7,976,861 for the nine months ended September 30, 2013 and 2012, respectively. The increase in cash used was driven primarily by an increase in net loss to \$14,871,661 for the first nine months of 2013 from \$6,415,705 for the first nine months of 2012. In the first nine months of 2013, cash used in operating activities was also affected by noncash expenses totaling \$1,822,288 and changes in operating assets and liabilities that decreased cash by \$244,654. In the first nine months of 2012, cash used in operating activities resulted from the net loss of \$6,415,705, noncash expenses totaling \$1,642,255 and changes in operating assets and liabilities which decreased cash by \$3,203,411, most of which resulted from the decrease in deferred revenue of \$4,143,463 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 Provided by (Used in) Investing Activities

Net cash provided by investing activities was \$3,501,713 in the first nine months of 2013 compared to net cash used of \$8,786,501 in the first nine months of 2012. Cash used for purchases of equipment, molds, furniture and fixtures in the nine-month periods ended September 30, 2013 and 2012 was \$2,184,568 and \$2,425,454, respectively, primarily related to OTREXUP commercial molds and assembly equipment. At September 30, 2013 and 2012, costs of \$437,504 and \$358,828, respectively, related primarily to OTREXUP commercial molds and equipment were recorded in the consolidated balance sheet in equipment, molds, furniture and fixtures and in accounts payable. For purposes of the consolidated statement of cash flows these costs were treated as non-cash investing activities

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and therefore were not included in cash used in investing activities. Additions to patent rights were \$195,558 in 2013 compared to \$283,871 in 2012. In the first nine months of 2013 we used cash of \$9,118,161 to purchase investment securities and received proceeds of \$15,000,000 from the maturities of investment securities. In the first nine months of 2012 we used cash of \$15,077,176 to purchase investment securities and received proceeds of \$9,000,000 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 nine months of 2013 and 2012 was \$652,282 and \$9,572,807, respectively. In the first nine months of 2013 we received proceeds of \$261,799 and \$494,812 from the exercise of 234,541 warrants and 707,285 options, respectively. In the first nine months of 2012 we received proceeds of \$8,962,270 and \$639,453 from the exercise of 5,231,135 warrants and 1,034,636 options, respectively. In the first nine 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.

Research and Development Programs

Our current research and development activities are primarily related to OTREXUP[®], Vibe[®] QST and device development projects.

OTREXUP[®]. OTREXUP[®] is being developed for subcutaneous administration of methotrexate to enhance the treatment of rheumatoid arthritis (RA), poly-articular-course juvenile RA and psoriasis. On October 14, 2013 we announced the approval of OTREXUP[®] (methotrexate) injection by the FDA. OTREXUP[®] is the first FDA approved subcutaneous methotrexate for once weekly self-administration with an easy-to-use, single dose, disposable auto injector. OTREXUP[®] is indicated for adults with severe active rheumatoid arthritis who have had an insufficient therapeutic response to or are intolerant of an adequate trial of first line therapy including full dose non-steroidal anti-inflammatory agents, or children with active polyarticular juvenile idiopathic arthritis. The FDA also approved adult use of OTREXUP[®] for symptomatic control of severe recalcitrant, disabling psoriasis that is not adequately responsive to other forms of therapy.

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 Medi-Jet[®] device 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.

As of September 30, 2013, we have incurred external expenses of approximately \$13,100,000 in connection with our OTREXUP development program, of which approximately \$2,900,000 was incurred in 2013. We have also incurred costs for molds and assembly equipment of approximately \$5,000,000, of which \$2,400,000 was incurred in 2013, that has been capitalized and included in equipment, molds, furniture and fixtures at September 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 \$7,000,000.

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Vibex® QST. We are developing Vibex® QST for testosterone replacement therapy for men suffering from symptomatic testosterone deficiency and announced on September 16, 2013 that the first patients have been dosed in a clinical study evaluating testosterone administered weekly by subcutaneous injection via the Vibex® QST auto injector device. Up to 45 patients will be enrolled in the study at approximately eight investigative sites in the United States. We incurred total external costs of approximately \$3,000,000 in connection with the Vibex® QST program, of which approximately \$2,050,000 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 disposable pen is in the stage of development where devices are being evaluated in user studies and stability programs. Our development programs consist of the determination of the device design, development of prototype tooling, production of prototype devices for testing and clinical studies, performance of clinical studies, and development of commercial tooling and assembly.

As of September 30, 2013, excluding costs related to OTREXUP and Vibe® QST, we have incurred total external costs of approximately \$14,000,000 in connection with research and development activities associated with our auto and pen injectors, of which approximately \$2,400,000 was incurred in 2013. Approximately \$11,100,000 of the total costs of \$14,000,000 was initially deferred, of which approximately \$10,800,000 has been recognized as cost of sales and \$300,000 remains deferred as of September 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 limited 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 significant commercial sales or future milestone payments under these agreements.

Other research and development costs. In addition to the OTREXUP project, Vibe® QST project and the Teva related device development projects, we incur direct costs in connection with other research and development projects related to our technologies and indirect costs that include salaries, administrative and other overhead costs of managing our research and development projects. Total other research and development costs were approximately \$6,200,000 for the nine months ended September 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.

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

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our primary market risk exposure is foreign exchange rate fluctuations of the Swiss Franc to the U.S. dollar as the financial position and operating results of our subsidiaries in Switzerland are translated into U.S. dollars for consolidation. Our exposure to foreign exchange rate fluctuations also arises from transferring funds to our Swiss subsidiaries in Swiss Francs. In addition, we have exposure to exchange rate fluctuations between the Euro and the U.S. dollar in connection with a licensing agreement with Ferring, under which certain products sold to Ferring and royalties are denominated in Euros. Most of our product sales, including a portion of our product sales to Ferring, and our development and licensing fees and royalties are denominated in U.S. dollars, thereby significantly mitigating the risk of exchange rate fluctuations on trade receivables. We do not currently use derivative financial instruments to hedge against exchange rate risk. The effect of foreign exchange rate fluctuations on our financial results for the period ended September 30, 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.

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.

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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 |
|-------------|--|
| 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 |

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SIGNATURES

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

ANTARES PHARMA, INC.

November 6, 2013

/s/ Paul K. Wotton

Dr. Paul K. Wotton
President and Chief Executive Officer

November 6, 2013

/s/ Robert F. Apple

Robert F. Apple
Executive Vice President and Chief Financial Officer