

ANTARES PHARMA, INC.  
Form 10-Q  
November 05, 2015

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, 2015

Commission File Number 1-32302

ANTARES PHARMA, INC.

A Delaware Corporation IRS Employer Identification No. 41-1350192  
100 Princeton South, Suite 300

Ewing, New Jersey 08628

(609) 359-3020

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

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

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

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

Large accelerated filer

Accelerated filer

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

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

The number of shares outstanding of the registrant’s Common Stock, \$.01 par value, as of November 1, 2015 was 154,828,512.

ANTARES PHARMA, INC.

INDEX

|  | PAGE |
|--|------|
| PART I. <u>FINANCIAL INFORMATION</u>   | 3    |
| Item 1. <u>Financial Statements</u>  | 3    |
| <u>Consolidated Balance Sheets, as of September 30, 2015 (Unaudited) and December 31, 2014</u>                                   | 3    |
| <u>Consolidated Statements of Operations (Unaudited) for the three and nine months ended September 30, 2015 and 2014</u>         | 4    |
| <u>Consolidated Statements of Comprehensive Loss (Unaudited) for the three and nine months ended September 30, 2015 and 2014</u> | 5    |
| <u>Consolidated Statements of Cash Flows (Unaudited) for the nine months ended September 30, 2015 and 2014</u>                   | 6    |
| <u>Notes to Consolidated Financial Statements (Unaudited)</u>  | 7    |
| Item 2. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>                             | 15   |
| Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>  | 23   |
| Item 4. <u>Controls and Procedures</u>   | 24   |
| PART II. <u>OTHER INFORMATION</u>  | 24   |
| Item   |      |
| 1A. <u>Risk Factors</u>  | 24   |
| Item 6. <u>Exhibits</u>  | 25   |
| <u>SIGNATURES</u>  | 26   |

## PART I – FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS  
ANTARES PHARMA, INC.

## CONSOLIDATED BALANCE SHEETS

|  | September 30,<br>2015<br>(Unaudited) | December 31,<br>2014 |
|--|--------------------------------------|----------------------|
| <b>Assets</b>  |                                      |                      |
| <b>Current Assets:</b>   |                                      |                      |
| Cash   | \$35,880,958                         | \$34,028,889         |
| Short-term investments   | 12,008,939                           | 6,002,438            |
| Accounts receivable  | 6,558,074                            | 3,510,051            |
| Inventories  | 5,657,336                            | 5,859,924            |
| Deferred costs   | 519,376                              | 1,913,921            |
| Prepaid expenses and other current assets  | 2,023,907                            | 2,322,464            |
| <b>Total current assets</b>  | <b>62,648,590</b>                    | <b>53,637,687</b>    |
| Equipment, molds, furniture and fixtures, net  | 13,831,713                           | 10,828,741           |
| Patent rights, net   | 2,551,015                            | 2,885,024            |
| Goodwill   | 1,095,355                            | 1,095,355            |
| Long-term investments  | 3,006,531                            | —                    |
| Other assets   | 326,024                              | 325,955              |
| <b>Total Assets</b>  | <b>\$83,459,228</b>                  | <b>\$68,772,762</b>  |
| <b>Liabilities and Stockholders' Equity</b>  |                                      |                      |
| <b>Current Liabilities:</b>  |                                      |                      |
| Accounts payable   | \$2,392,929                          | \$10,071,504         |
| Accrued expenses and other liabilities   | 5,745,440                            | 5,635,559            |
| Deferred revenue   | 1,980,710                            | 8,520,517            |
| <b>Total current liabilities</b>   | <b>10,119,079</b>                    | <b>24,227,580</b>    |
| Deferred revenue – long term   | 719,400                              | 3,349,026            |
| <b>Total liabilities</b>   | <b>10,838,479</b>                    | <b>27,576,606</b>    |
| <b>Stockholders' Equity:</b>   |                                      |                      |
| Preferred Stock: \$0.01 par, authorized 3,000,000 shares, none outstanding   | —                                    | —                    |
| Common Stock: \$0.01 par; authorized 200,000,000 shares; 154,828,512 and<br>131,743,365 issued and outstanding at September 30, 2015 and December 31,<br>2014, |                                      |                      |
| respectively   | 1,548,285                            | 1,317,433            |
| Additional paid-in capital   | 294,252,003                          | 249,032,066          |
| Accumulated deficit  | (222,480,017)                        | (208,447,656)        |
| Accumulated other comprehensive loss   | (699,522 )                           | (705,687 )           |
|  | 72,620,749                           | 41,196,156           |
| <b>Total Liabilities and Stockholders' Equity</b>  | <b>\$83,459,228</b>                  | <b>\$68,772,762</b>  |

See accompanying notes to consolidated financial statements.



## ANTARES PHARMA, INC.

## CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

|   | For the Three Months Ended<br>September 30, |                | For the Nine Months Ended<br>September 30, |                 |
|---|---|----------------|--|-----------------|
|   | 2015  | 2014           | 2015                                       | 2014            |
| <b>Revenue:</b>   |   |                |  |                 |
| Product sales   | \$8,027,029                                 | \$3,559,579    | \$18,490,193                               | \$8,724,884     |
| Development revenue   | 2,608,336                                   | 1,744,735      | 8,024,184                                  | 4,954,285       |
| Licensing revenue   | 42,960                                      | 926,955        | 6,112,341                                  | 2,783,434       |
| Royalties   | 407,427                                     | 339,312        | 1,227,462                                  | 1,636,958       |
| Total revenue   | 11,085,752                                  | 6,570,581      | 33,854,180                                 | 18,099,561      |
| <b>Cost of revenue:</b>   |   |                |  |                 |
| Cost of product sales   | 3,265,983                                   | 2,158,266      | 7,763,734                                  | 5,021,896       |
| Cost of development revenue                                     | 1,833,780                                   | 349,100        | 5,718,852                                  | 792,295         |
| Total cost of revenue   | 5,099,763                                   | 2,507,366      | 13,482,586                                 | 5,814,191       |
| Gross profit  | 5,985,989                                   | 4,063,215      | 20,371,594                                 | 12,285,370      |
| <b>Operating expenses:</b>                                      |   |                |  |                 |
| Research and development  | 5,142,387                                   | 4,426,730      | 14,089,100                                 | 12,903,304      |
| Selling, general and administrative                             | 6,611,169                                   | 6,810,089      | 20,253,489                                 | 24,455,167      |
| Total operating expenses  | 11,753,556                                  | 11,236,819     | 34,342,589                                 | 37,358,471      |
| Operating loss  | (5,767,567 )                                | (7,173,604 )   | (13,970,995 )                              | (25,073,101 )   |
| Other income (expense)  | 29,526                                      | (12,837 )      | (61,366 )                                  | (5,670 )        |
| Net loss  | \$(5,738,041 )                              | \$(7,186,441 ) | \$(14,032,361 )                            | \$(25,078,771 ) |
| Basic and diluted net loss per common share                     | \$(0.04 )                                   | \$(0.05 )      | \$(0.10 )                                  | \$(0.19 )       |
| Basic and diluted weighted average common shares<br>outstanding | 154,808,641                                 | 130,771,380    | 143,819,033                                | 130,163,929     |

See accompanying notes to consolidated financial statements.

ANTARES PHARMA, INC.

## CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(UNAUDITED)

|   | For the Three Months<br>Ended<br>September 30, |               | For the Nine Months Ended<br>September 30, |                |
|---|--|---------------|--|----------------|
|   | 2015   | 2014          | 2015                                       | 2014           |
| Net loss                                | \$(5,738,041)                                  | \$(7,186,441) | \$(14,032,361)                             | \$(25,078,771) |
| Foreign currency translation adjustment | (22,044 )                                      | (32,114 )     | 6,165                                      | (32,204 )      |
| Comprehensive loss                      | \$(5,760,085)                                  | \$(7,218,555) | \$(14,026,196)                             | \$(25,110,975) |

See accompanying notes to consolidated financial statements.

## ANTARES PHARMA, INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

|   | For the Nine Months Ended<br>September 30, |                |
|---|--|----------------|
|   | 2015                                       | 2014           |
| <b>Cash flows from operating activities:</b>  |  |                |
| Net loss  | \$(14,032,361)                             | \$(25,078,771) |
| <b>Adjustments to reconcile net loss to net cash used in operating activities:</b>        |  |                |
| Depreciation and amortization   | 1,169,745                                  | 873,158        |
| Loss on disposal of equipment   | 167,097                                    | —              |
| Stock-based compensation expense  | 2,649,062                                  | 1,898,241      |
| Amortization of premiums and discounts  | 7,070                                      | 19,259         |
| <b>Changes in operating assets and liabilities:</b>                                       |  |                |
| Accounts receivable   | (3,045,011 )                               | (1,237,907 )   |
| Inventories   | 202,588                                    | (1,531,910 )   |
| Prepaid expenses and other current assets   | 316,315                                    | 776,389        |
| Deferred costs  | 1,394,545                                  | (1,313,724 )   |
| Other assets  | —  | 276            |
| Accounts payable  | (5,742,113 )                               | (220,962 )     |
| Accrued expenses and other current liabilities  | 236,434                                    | 605,211        |
| Deferred revenue  | (9,173,966 )                               | 4,733,129      |
| Net cash used in operating activities   | (25,850,595)                               | (20,477,611)   |
| <b>Cash flows from investing activities:</b>  |  |                |
| Purchases of equipment, molds, furniture and fixtures                                     | (5,013,012 )                               | (2,829,738 )   |
| Additions to patent rights  | (1,008,363 )                               | (461,943 )     |
| Proceeds from maturities of investment securities   | 6,000,000                                  | 21,000,000     |
| Purchases of investment securities  | (15,037,675)                               | —              |
| Net cash provided by (used in) investing activities                                       | (15,059,050)                               | 17,708,319     |
| <b>Cash flows from financing activities:</b>  |  |                |
| Proceeds from issuance of common stock, net   | 42,850,677                                 | —              |
| Proceeds from exercise of stock options and warrants                                      | —  | 2,908,540      |
| Taxes paid related to net share settlement of equity awards                               | (87,770 )                                  | (154,397 )     |
| Net cash provided by financing activities   | 42,762,907                                 | 2,754,143      |
| Effect of exchange rate changes on cash   | (1,193 )                                   | (1,255 )       |
| Net increase (decrease) in cash   | 1,852,069                                  | (16,404 )      |
| <b>Cash:</b>  |  |                |
| Beginning of period   | 34,028,889                                 | 39,067,236     |
| End of period   | \$35,880,958                               | \$39,050,832   |
| <b>Supplemental disclosure of non-cash investing activities:</b>                          |  |                |
| <b>Purchases of equipment, molds, furniture and fixtures recorded in accounts payable</b> |  |                |
| and accrued expenses  | \$42,758                                   | \$526,137      |
| Additions to patent rights recorded in accounts payable and accrued expenses              | \$—  | \$1,423,227    |



See accompanying notes to consolidated financial statements.

ANTARES PHARMA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

### 1. Description of Business

Antares Pharma, Inc. (“Antares” or the “Company”) is an emerging, specialty pharmaceutical company focusing on the development and commercialization of self-administered parenteral pharmaceutical products and technologies. The Company has multiple internal product development programs as well as numerous partnership arrangements with several industry leading pharmaceutical companies. The Company has formed significant strategic alliances with Teva Pharmaceutical Industries, Ltd. (“Teva”), Ferring Pharmaceuticals Inc. and Ferring B.V. (together “Ferring”), and JCR Pharmaceuticals Co., Ltd. (“JCR”). Through these relationships, the Company develops and applies its drug delivery systems in collaborations with the pharmaceutical partners to enhance the partners' drug compounds and delivery methods.

The Company develops and manufactures, for itself and with its partners, novel, pressure-assisted injector devices, with and without needles, which allow patients to self-inject drugs. It makes a reusable, needle-free spring action injection device which is marketed through its partners for use with human growth hormone (hGH). The Company has also developed variations of the needle-free injector by adding a small shielded needle to a pre-filled, single-use disposable injector, called the VIBEX® pressure assisted auto injection system. This system is an alternative to the needle-free system for use with injectable drugs in unit dose containers and is suitable for branded and generic injectables. Additionally, the Company developed a disposable multi-dose pen injector for use with standard cartridges, and has a portfolio of gel-based products which are commercialized through various partners.

In February 2014, the Company launched its product OTREXUP™ (methotrexate) injection, which is the first subcutaneous methotrexate for once weekly self-administration with an easy-to-use, single dose, disposable auto injector approved by the U.S. Food and Drug Administration (“FDA”). OTREXUP™ is indicated for adults with severe active rheumatoid arthritis (“RA”), children with active polyarticular juvenile idiopathic arthritis and adults with severe recalcitrant psoriasis. To date, Antares has received FDA approval for dosage strengths of 7.5 mg, 10 mg, 15 mg, 20 mg and 25 mg of OTREXUP™.

The Company has other products at various stages of development and approval. Antares is developing VIBEX® Sumatriptan for the acute treatment of migraines and has begun commercial scale tooling and mold fabrication in anticipation of a potential approval and launch. The Company is currently conducting clinical studies of VIBEX® QuickShot® Testosterone (“QS T”), for testosterone replacement therapy, and has also initiated manufacturing development work for QS M, a combination product for an undisclosed central nervous system indication.

### 2. Basis of Presentation and Significant Accounting Policies

The accompanying unaudited consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the U.S. for interim financial information and with the instructions to Form 10-Q

and Article 10 of the Securities and Exchange Commission's Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the U.S. for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. The accompanying consolidated financial statements and notes thereto should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended December 31, 2014. Operating results for the three and nine months ended September 30, 2015 are not necessarily indicative of the results that may be expected for the year ending December 31, 2015.

Certain prior year amounts have been reclassified in the consolidated financial statements to conform to the current year presentation. These reclassifications were made to present selling, general and administrative expenses in one line in the consolidated statements of operations. In prior years, sales and marketing expenses and general and administrative expenses were presented in separate lines. These reclassifications have no effect on previously reported net income or total operating expenses.

#### Investments

All short-term and long-term investments are U.S. Treasury bills or U.S. Treasury notes that are classified as held-to-maturity because of the Company's positive intent and ability to hold the securities to maturity. The securities are carried at their amortized cost and the fair value of all securities is determined by quoted market prices. At September 30, 2015 and December 31, 2014, the Company's short-term investments had a carrying value of \$12,008,939 and \$6,002,438, respectively. As of September 30, 2015, the Company had long-term investments with a carrying value of \$3,006,531, and held no long-term

investments as of December 31, 2014. The carrying value of the Company's short-term and long-term investments as of September 30, 2015 and December 31, 2014 approximated fair value.

### Inventories

Inventories are stated at the lower of cost or market. Cost is determined on a first-in, first-out basis. Certain components of the Company's products are provided by a limited number of vendors, and the Company's production, assembly, warehousing and distribution operations are outsourced to third-parties where substantially all of the Company's inventory is located. Disruption of supply from key vendors or third-party suppliers may have a material adverse impact on the Company's operations. The Company provides reserves for potentially excess, dated or obsolete inventories based on an analysis of inventory on hand compared to forecasts of future sales. Inventories consist of the following:

|                     | September<br>30,<br>2015 | December<br>31,<br>2014 |
|---------------------|--------------------------|-------------------------|
| <b>Inventories:</b> |                          |                         |
| Raw material        | \$236,924                | \$461,396               |
| Work in process     | 3,171,074                | 3,896,837               |
| Finished goods      | 2,249,338                | 1,501,691               |
|                     | <b>\$5,657,336</b>       | <b>\$5,859,924</b>      |

### Capitalized Patent Costs

The Company capitalizes external legal patent defense costs and costs for pursuing patent infringements when it determines that a successful outcome is probable and will lead to an increase in the value of the patent. The capitalized costs are amortized over the remaining life of the related patent. If changes in the anticipated outcome were to occur that reduce the likelihood of a successful outcome of the entire action to less than probable, the capitalized costs would be charged to expense in the period in which the change is determined. As of September 30, 2015 and December 31, 2014, approximately \$1,800,000 in external legal patent defense costs were capitalized within patent rights, net.

### Product Revenue

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

The Company recognized \$3,592,779 and \$9,943,182 in OTREXUP™ product revenue for the three and nine months ended September 30, 2015, respectively, as compared to \$2,606,973 and \$4,491,288 for the three and nine months ended September 30, 2014, which is presented net of product allowances for estimated wholesaler discounts, prompt pay discounts, chargebacks, rebates and patient discount programs. The Company had deferred revenue balances of \$954,401 and \$1,061,947 at September 30, 2015 and December 31, 2014, respectively, for OTREXUP™ product shipments, which is net of product sales allowances.

The Company will continue to recognize revenue upon the earlier to occur of prescription units dispensed or expiration of the right of return until it can reliably estimate product returns, at which time the Company will record a one-time increase in net revenue related to the recognition of revenue previously deferred. In addition, the costs of manufacturing OTREXUP™ associated with the deferred revenue are recorded as deferred costs, which are included in inventory, until such time as the related deferred revenue is recognized.

#### Product Sales Allowances

The Company recognizes product sales allowances as a reduction of product sales in the same period the related revenue is recognized. Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with customers and third-party payors and the levels of inventory within the

distribution channels that may result in future rebates or discounts taken. In certain cases, such as patient support programs, the Company recognizes the cost of patient discounts as a reduction of revenue based on estimated utilization. If actual future results vary, it may be necessary to adjust these estimates, which could have an effect on product revenue in the period of adjustment. Product sales allowances include:

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

**Prompt Pay Discounts.** The Company offers cash discounts to its customers, generally 2% of the sales price, as an incentive for prompt payment. The Company accounts for cash discounts by reducing accounts receivable by the prompt pay discount amount and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.

**Chargebacks.** The Company provides discounts to authorized users of the Federal Supply Schedule (“FSS”) of the General Services Administration under an FSS contract negotiated by the Department of Veterans Affairs and various organizations under Medicaid contracts and regulations. These entities purchase products from the wholesale distributors at a discounted price, and the wholesale distributors then charge back to the Company the difference between the current wholesale acquisition cost and the price the entity paid for the product. The Company estimates and accrues chargebacks based on estimated wholesaler inventory levels, current contract prices and historical chargeback activity. Chargebacks are recognized as a reduction of revenue in the same period the related revenue is recognized.

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

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

### 3. Licensing Agreements and Contractual Arrangements

The Company has entered into multiple license agreements for its devices with Teva. The Company’s development projects in collaboration with Teva include VIBEX® Epinephrine, an exenatide multi-dose pen, and another undisclosed multi-dose pen. In December 2014, Teva submitted the final amendment to the VIBEX® Epinephrine ANDA, and FDA accepted Teva’s filing of an ANDA in October 2014 for exenatide, formerly referred to as Teva “Pen 2”.

Antares is also developing VIBEX® Sumatriptan for the acute treatment of migraines which, if approved will be distributed by Teva. The Company received a complete response letter from the FDA regarding its Abbreviated New

Drug Application (“ANDA”) for VIBEX® Sumatriptan, providing revisions to labelling and citing minor deficiencies. The Company submitted its response to the FDA in March, 2015, and received a second complete response letter from the FDA primarily requesting additional labeling revisions, to which it responded in July 2015. Commercial scale tooling and mold fabrication has begun in anticipation of potential approval and launch.

The Company also makes a reusable, needle-free, spring-action injector device, which is marketed for use with human growth hormone, hGH, through licenses to its pharmaceutical partners Ferring and JCR, which generates product sales and royalties. Ferring commercializes the Company’s needle-free injection system with their 4 mg and 10 mg hGH formulations marketed as Zomajet® 2 Vision and Zomajet® Vision X worldwide. Ferring purchased the U.S. rights to TEV-TROPIN® (Teva’s hGH), and Tjet® from Teva in December 2014. In March 2015, Ferring received FDA approval of a name change enabling TEV-TROPIN® to be marketed in the U.S. as ZOMACTON™(somatropin [rDNA origin]) for injection and the Tjet® needle-free delivery system to be marketed in the U.S. as ZOMA-Jet.™ Also in March 2015, Ferring received approval from the FDA to market the 10 mg needle free injector device which, along with certain consumables, is supplied by Antares to Ferring. Distribution of growth hormone injectors occurs in the U.S., Europe, Japan and other Asian countries through pharmaceutical company relationships.

Antares has a portfolio of gel-based products which are marketed through licensing agreements. Actavis plc (“Actavis”) is currently marketing Gelnique® (oxybutynin chloride), 3% gel, which is indicated in the U.S. for the treatment of overactive bladder. Elestrin® (estradiol gel) is currently marketed by Meda Pharmaceuticals, Inc. (“Meda”) in the U.S. for the treatment of moderate-to-severe vasomotor symptoms associated with menopause.

#### LEO Pharma Promotion and License Agreement

In November 2013, the Company entered into a promotion and license agreement with LEO Pharma (“LEO”), under which the Company granted LEO the exclusive right to promote OTREXUP™ to dermatologists for symptomatic control of psoriasis in adults in the U.S. The Company received a non-refundable upfront payment of \$5,000,000 and a subsequent milestone payment of \$5,000,000 pursuant to the terms of the agreement. The deliverables in the agreement were accounted for as a single unit of accounting, and the \$10,000,000 in total payments received were recorded as deferred revenue and were being amortized to licensing revenue over a three-year period.

Effective June 23, 2015, the agreement with LEO was terminated and the Company regained the exclusive U.S. marketing rights to OTREXUP™. As a result, the Company recognized the remaining unamortized balance of the deferred revenues related to this arrangement in the second quarter of 2015. Deferred revenue in connection with this agreement was \$6,000,000 at December 31, 2014. The Company recognized zero and \$857,143 in licensing revenue for the three month periods ended September 30, 2015 and 2014, respectively, and \$6,000,000 and \$2,571,429 in licensing revenue for the nine month periods ended September 30, 2015 and 2014, respectively in connection with this agreement and its subsequent termination.

#### 4. Stockholders’ Equity

On May 11, 2015, the Company completed an underwritten offering of 23,000,000 shares of its common stock at a price to the public of \$2.00 per share. The Company received net proceeds of approximately \$42.9 million after deducting underwriting discounts, commissions and offering expenses paid by the Company. The Company intends to use the net proceeds from the offering for general corporate purposes including business development, in-licensing and acquisitions.

#### Equity Compensation Plan

The Company’s 2008 Equity Compensation Plan (the “Plan”) allows for grants in the form of incentive stock options, nonqualified stock options, stock units, stock awards, stock appreciation rights, and other stock-based awards. All of the Company’s officers, directors, employees, consultants and advisors are eligible to receive grants under the Plan. The maximum number of shares authorized for issuance under the Plan is 21,000,000 and the maximum number of shares of stock that may be granted to any one participant during a calendar year is 1,000,000 shares. Options to purchase shares of common stock are granted at exercise prices not less than 100% of fair market value on the dates of grant. The term of each option is ten years and the options typically vest in quarterly installments over a three-year period. As of September 30, 2015, the Plan had 852,808 shares available for grant.

#### Stock Options

A summary of stock option activity under the Plan as of September 30, 2015, and the changes during the nine months then ended is as follows:

|          | Weighted  |           |
|----------|-----------|-----------|
| Weighted | Average   |           |
| Average  | Remaining | Aggregate |



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

|                                   | Number of<br>Shares | Exercise<br>Price (\$) | Contractual<br>Term<br>(Years) | Intrinsic<br>Value (\$) |
|-----------------------------------|---------------------|------------------------|--------------------------------|-------------------------|
| Outstanding at December 31, 2014  | 7,245,485           | 2.25                   |                                |                         |
| Granted                           | 2,959,010           | 2.23                   |                                |                         |
| Exercised                         | —                   | —                      |                                | —                       |
| Cancelled/Forfeited               | (633,416 )          | 2.91                   |                                |                         |
| Outstanding at September 30, 2015 | 9,571,079           | 2.20                   | 6.9                            | 1,581,795               |
| Exercisable at September 30, 2015 | 6,188,948           | 2.07                   | 5.6                            | 1,581,795               |

The per share weighted average fair values of all options granted during the first nine months of 2015 and 2014 were estimated as \$1.13 and \$3.08, respectively, on the date of grant using the Black-Scholes option pricing model based on the assumptions noted in the table below. Expected volatilities are based on the historical volatility of the Company's stock price. The weighted average expected life is based on both historical and anticipated employee behavior.

|  | September<br>30, |        |
|--|------------------|--------|
|  | 2015             | 2014   |
| Risk-free interest rate                  | 1.3 %            | 1.7 %  |
| Annualized volatility                    | 53.5 %           | 62.0 % |
| Weighted average expected life, in years | 6.0              | 6.0    |
| Expected dividend yield                  | 0.0 %            | 0.0 %  |

There were no stock option exercises in the first nine months of 2015. In the first nine months of 2014, 1,991,728 stock options with a weighted average exercise price of \$1.19 were exercised which generated proceeds of \$2,363,425 to the Company.

Total recognized compensation expense for stock options was \$2,177,067 and \$1,451,031 for the first nine months of 2015 and 2014, respectively, and totaled \$766,062 and \$643,304 for the three month periods ended September 30, 2015 and 2014, respectively. As of September 30, 2015, there was \$3,678,779 of total unrecognized compensation cost related to nonvested outstanding stock options that is expected to be recognized over a weighted average period of approximately 2.01 years.

#### Long Term Incentive Program (LTIP)

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

The stock options have a ten-year term, have an exercise price equal to the closing price of the Company's common stock on the date of grant, vest in quarterly installments over three years, were otherwise granted on the same standard terms and conditions as other stock options granted pursuant to the Plan and are included in the stock options table above. The RSUs vest in three equal annual installments. The PSU awards made to the senior executives vest and convert into shares of the Company's common stock based on the Company's attainment of certain performance goals over a performance period of three years.

The performance stock unit awards and restricted stock unit awards granted under the long term incentive program are summarized in the following table:

| Performance Stock Units |          | Restricted Stock Units |          |
|-------------------------|----------|------------------------|----------|
| Number                  | Weighted | Number                 | Weighted |
| of                      |          | of                     |          |

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

|                                   | Shares    | Average Grant | Shares    | Average Grant |
|-----------------------------------|-----------|---------------|-----------|---------------|
|                                   |           | Date Fair     |           | Date Fair     |
|                                   |           | Value (\$)    |           | Value (\$)    |
| Outstanding at December 31, 2014  | 463,542   | 3.08          | 231,124   | 3.07          |
| Granted                           | 664,391   | 2.09          | 664,391   | 2.18          |
| Vested/settled                    | —         |               | (112,285) | 3.24          |
| Forfeited/expired                 | (167,583) | 2.65          | (68,402 ) | 2.47          |
| Outstanding at September 30, 2015 | 960,350   | 2.41          | 714,828   | 2.32          |

In 2015 and 2014, the LTIP awards include PSUs that will be earned based on the Company's total shareholder return ("TSR") as compared to the Nasdaq Biotechnology Index ("NBI") at the end of the performance period, which performance period is January 1, 2014 to December 31, 2016 for the 2014 award and January 1, 2015 to December 31, 2017 for the 2015 award. Depending on the outcome of the performance goal, a recipient may ultimately earn a number of shares greater or less than their target number of shares granted, ranging from 0% to 150% of the PSUs granted. The fair values of the TSR PSUs granted in May 2015 and 2014 was determined using a Monte Carlo simulation and utilized the following inputs and assumptions:

|                                   | 2015    | 2014    |
|-----------------------------------|---------|---------|
|                                   | Award   | Award   |
| Closing stock price on grant date | \$2.18  | \$3.09  |
| Performance period starting price | \$2.57  | \$4.08  |
| Term of award (in years)          | 2.59    | 2.59    |
| Volatility                        | 60.45 % | 50.87 % |
| Risk-free interest rate           | 0.83 %  | 0.61 %  |
| Expected dividend yield           | 0.00 %  | 0.00 %  |
| Fair value per TSR PSU            | \$1.71  | \$2.64  |

The performance period starting price is measured as the average closing price over the last 20 trading days prior to the performance period start. The Monte Carlo simulation model also assumed correlations of returns of the prices of the Company's common stock and the common stocks of the NBI companies and stock price volatilities of the NBI companies. The fair value of the target number of shares that can be earned under the TSR PSUs is being recognized as compensation expense over the performance period.

Total compensation expense recognized in connection with PSU awards totaled \$89,911 in the first nine months of 2015. The Company recognized a net expense reduction of \$55,463 in the first nine months of 2014 due to the forfeiture of PSU awards in connection with the departure of senior executives. Compensation expense recognized in the first nine months of 2015 and 2014 in connection with the RSUs was \$382,084 and \$146,866, respectively.

Shares issued in connection with PSU and RSU awards that vested in the first nine months of 2015 and 2014 were net-share settled such that the Company withheld shares with a 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 to satisfy tax obligations were 39,665 and 38,768 in the nine months ended September 30, 2015 and 2014, respectively, and were based on the fair 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 \$87,770 and \$154,397 in the nine months ended September 30, 2015 and 2014, respectively, and are reflected as a financing activity within the consolidated statements of cash flows. These net-share settlements had the effect of share repurchases by the Company as they reduced the number of shares that would have otherwise been issued as a result of the vesting and did not represent an expense to the Company.

#### Warrants

In the first nine months of 2014, the Company received proceeds of \$545,115 from the exercise of 545,100 warrants. There were no warrants outstanding at September 30, 2015 or December 31, 2014.

## Stock Awards

At times, the Company makes discretionary grants of its common stock to members of management and other employees in lieu of cash bonus awards or in recognition of special achievements. There were no discretionary grants of common stock in the first nine months of 2015. In the first nine months of 2014, there were 150,000 shares of common stock granted to members of executive management as bonus compensation for achievements in 2013.

## 5. 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 excluded from dilutive loss per share because their effect was anti-dilutive totaled 9,571,079 and 7,107,190 at September 30, 2015 and 2014, respectively.

## 6. 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 |             | Nine Months Ended |              |
|--------------------------|--------------------|-------------|-------------------|--------------|
|                          | September 30,      |             | September 30,     |              |
|                          | 2015               | 2014        | 2015              | 2014         |
| United States of America | \$9,740,486        | \$5,823,339 | \$30,055,925      | \$14,310,806 |
| Europe                   | 1,309,731          | 735,613     | 3,609,798         | 3,565,616    |
| Other                    | 35,535             | 11,629      | 188,457           | 223,139      |
|                          | \$11,085,752       | \$6,570,581 | \$33,854,180      | \$18,099,561 |

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

|                         | Three Months Ended |             | Nine Months Ended |             |
|-------------------------|--------------------|-------------|-------------------|-------------|
|                         | September 30,      |             | September 30,     |             |
|                         | 2015               | 2014        | 2015              | 2014        |
| Teva                    | \$5,097,912        | \$1,779,595 | \$12,227,129      | \$6,084,408 |
| LEO Pharma              | —                  | 857,143     | 6,000,000         | 2,571,429   |
| McKesson <sup>(1)</sup> | 2,105,422          | 1,489,699   | 5,440,323         | 1,916,957   |
| Ferring                 | 1,309,731          | 734,013     | 3,609,798         | 3,564,021   |

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

## 7. Legal Proceedings

In the first quarter of 2014, medac Pharma, Inc. (“Medac Pharma”) announced that it submitted a New Drug Application (“NDA”) to the FDA for an auto-pen containing methotrexate. On February 28, 2014, Antares filed a complaint against Medac Pharma and medac GmbH, the parent company of Medac Pharma, (medac GmbH, together with Medac Pharma, “Medac”) in the U.S. District Court for the District of Delaware, alleging infringement of two of the Company’s patents for technology regarding an auto injector and an auto injector containing methotrexate. On March 14, 2014, Antares filed a motion for preliminary injunction seeking to enjoin Medac from selling its methotrexate auto-pen product if and when such product is approved for sale in the United States, pending the final resolution of the litigation. On April 18, 2014 an amended complaint was filed asserting four Antares patents, and the motion for preliminary injunction was updated. On July 10, 2014, the District Court denied Antares’ motion for preliminary injunction. Antares filed an appeal of the denial of the motion for preliminary injunction with the U.S. Court of Appeals for the Federal Circuit, and in February 2015, that motion was denied. In 2014, a total of approximately

\$1,800,000 in legal costs in connection with this suit was capitalized.

On March 7, 2014, Medac filed suit against Antares, LEO Pharma, Inc. and its parent company, LEO Pharma A/S (LEO Pharma, Inc. together with LEO Pharma A/S, the “LEO Entities”) in the U.S. District Court for the District of New Jersey, alleging that Antares and the LEO Entities infringe Medac Pharma’s U.S. Patent 8,664,231 (the “231 patent”) that was issued by the U.S. Patent and Trademark Office on March 4, 2014. Under the terms of the promotion and license agreement between the Company and the LEO Entities, the Company agreed to indemnify the LEO Entities from claims that OTREXUP™ infringes the intellectual property rights of any third party. On July 1, 2014, Antares filed a petition with the Patent Trial and Appeal Board (the “PTAB”) of the U.S. Patent and Trademark Office seeking an inter partes review of the 231 patent, and in January 2015, the PTAB decided to institute review of the 231 patent. Legal costs in connection with this suit and the inter partes review were expensed as incurred.

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

#### 8. Recent Accounting Pronouncements

In July 2015, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (ASU) No. 2015-11, Simplifying the Measurement of Inventory. The new standard changes the measurement principle for inventory from the lower of cost or market to lower of cost and net realizable value. The standard is effective for public entities for annual and interim periods beginning after December 15, 2016. Early adoption is permitted. Entities are required to disclose the nature and reason for the change in accounting principle in the first interim and annual period of adoption. The Company is currently evaluating the impact of this standard on its consolidated results of operations and financial position.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (“ASU No. 2014-09”). This guidance requires an entity to recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard creates a five-step model that requires a company to: identify customer contracts, identify the separate performance obligations, determine the transaction price, allocate the transaction price to the separate performance obligations and recognize revenue when each performance obligation is satisfied. This guidance also requires an entity to disclose sufficient information to enable users of financial statements to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. Qualitative and quantitative information is required about:

- Contracts with customers—including revenue and impairments recognized, disaggregation of revenue and information about contract balances and performance obligations (including the transaction price allocated to the remaining performance obligations).
- Significant judgments and changes in judgments—determining the timing of satisfaction of performance obligations (over time or at a point in time), and determining the transaction price and amounts allocated to performance obligations.
- Certain assets—assets recognized from the costs to obtain or fulfill a contract.

In August 2015, the FASB issued ASU 2015-14 which defers the effective date of ASU No. 2014-09 by one year to annual reporting periods beginning after December 15, 2017, including interim periods within that year. The standard allows for either full retrospective adoption, where the standard is applied to all periods presented, or modified retrospective adoption where the standard is applied only to the most current period presented in the financial statements. Early adoption of ASU 2014-09 is permitted but not before the original effective date (annual periods beginning after December 15, 2016). The Company is currently evaluating the impact of the adoption of this standard on its consolidated results of operations and financial position.

#### 9. Subsequent Event

On October 5, 2015, the Company received a written notice of termination of its licensing agreement (the “Agreement”) with Pfizer Consumer Healthcare (“Pfizer”) for one of its drug delivery technologies. Pfizer informed the Company that the product Pfizer was developing failed to meet pre-specified endpoints in a clinical study. The Agreement will terminate on November 5, 2015.





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

Forward-Looking Statements

Certain statements in this report, including statements in the management's discussion and analysis section set forth below, may be considered "forward-looking statements" as that term is defined in the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by the words "expect," "estimate," "project," "anticipate," "should," "intend," "may," "will," "believe," "continue" or other words and terms of similar meaning in connection with 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 commercialization of OTREXUP™ (methotrexate) injection for subcutaneous use;
- our expectations regarding product development including clinical trial results, and potential approval by the United States ("U.S.") Food and Drug Administration ("FDA") of VIBEX® QuickShot Testosterone injection ("VIBEX® QS T");
- our expectations regarding continued product development with Teva Pharmaceutical Industries, Ltd. ("Teva");
- our expectations regarding product development and potential FDA approval of VIBEX® Sumatriptan (sumatriptan injection);
- our expectations regarding product development and potential FDA approval of VIBEX® Epinephrine Pen ("epinephrine auto injector") and Teva's ability to successfully commercialize the epinephrine auto injector;
- our expectations regarding trends in pharmaceutical drug delivery characteristics;
- our anticipated continued reliance on contract manufacturers to manufacture our products;
- our sales and marketing plans;
- product development and commercialization plans regarding our other products and product candidates;
- timing and results of our clinical trials;
- our plans regarding potential manufacturing and marketing partners;
- our future cash flow and our ability to support our operations;
- the impact of new accounting pronouncements and our expectations and estimates with regard to current accounting practices; and
- our expectations regarding the year ending December 31, 2015.

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

- delays in product introduction and marketing or interruptions in supply;
- a decrease in business from our major customers and partners;
  - our inability to compete successfully against new and existing competitors or to leverage our research and development capabilities and our marketing capabilities;
- our inability to effectively market our services or obtain and maintain arrangements with our customers, partners and manufacturers;
- our inability to effectively protect our intellectual property;
- costs associated with future litigation and the outcome of such litigation;
- our inability to attract and retain key personnel;
- regulatory changes or delays in the regulatory process;



- adverse economic and political conditions; and
- our inability to obtain additional financing, reduce expenses or generate funds when necessary.

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

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

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

#### Overview

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

We develop and manufacture for ourselves and with partners, novel, pressure-assisted injectors, with and without needles, which allow patients to self-inject drugs. We make a reusable, needle-free spring action injection device which is marketed through our partners for use with human growth hormone (hGH). We have developed variations of the needle-free injector by adding a small shielded needle to a pre-filled, single-use disposable injector, called the VIBEX® pressure assisted auto injection system. This system is an alternative to the needle-free system for use with injectable drugs in unit dose containers and is suitable for branded and generic injectables. Additionally, we have developed a disposable multi-dose pen injector for use with standard cartridges, and have a portfolio of gel-based products that are commercialized through various partners.

In February 2014, we launched our product OTREXUP™, which is the first FDA approved subcutaneous methotrexate for once weekly self-administration with an easy-to-use, single dose, disposable auto injector. OTREXUP™ is indicated for adults with severe active rheumatoid arthritis (“RA”), children with active polyarticular juvenile idiopathic arthritis and adults with severe recalcitrant psoriasis (“psoriasis”). To date, we have received FDA approval for dosage strengths of 7.5 mg, 10 mg, 15 mg, 20 mg and 25 mg of OTREXUP™. We have worldwide marketing rights for OTREXUP™ and commercialize OTREXUP™ on our own in the U.S. for the treatment of RA. We previously provided LEO Pharma A/S (“LEO Pharma”) an exclusive license to commercialize OTREXUP™ in the U.S. for the treatment of psoriasis. As discussed in Note 3 to the Consolidated Financial Statements, the agreement with LEO Pharma was terminated effective June 23, 2015, at which time we regained the exclusive marketing rights in the U.S. for the treatment of psoriasis.

We have formed significant strategic alliances with several leading pharmaceutical companies including Teva Pharmaceutical Industries, Ltd. (“Teva”), Ferring Pharmaceuticals Inc. and Ferring B.V. (together “Ferring”), and JCR Pharmaceuticals Co., Ltd. (“JCR”). Through these relationships, we develop and apply our drug delivery systems in collaborations with the pharmaceutical partners to enhance the partners' drug compounds and delivery methods.

We make a reusable, needle-free, spring-action injector device known as the Tjet<sup>®</sup> and Zomajet<sup>®</sup>, which is marketed for use with human growth hormone (“hGH”). We have achieved distribution of our devices for use with hGH through licensing arrangements with our pharmaceutical partners Ferring and JCR, resulting in product sales and royalties for the company. Ferring commercializes our needle-free injection system with their 4 mg and 10 mg hGH formulations marketed as Zomajet<sup>®</sup> 2 Vision and Zomajet<sup>®</sup> Vision X worldwide. Ferring purchased the U.S. rights to TEV-TROPIN<sup>®</sup> (Teva's hGH) and Tjet<sup>®</sup>, in December 2014 from Teva. In March 2015, Ferring received FDA approval of a name change enabling TEV-TROPIN<sup>®</sup> to be marketed in the U.S. as ZOMACTON<sup>™</sup>(somatropin [rDNA origin]) for injection and the Tjet<sup>®</sup> needle-free delivery system to be marketed in the U.S. as ZOMA-Jet.<sup>™</sup> Also in March 2015, Ferring received approval from the FDA to market the 10 mg needle free injector device which, along with certain consumables, is supplied by Antares to Ferring. Distribution of growth hormone injectors occurs in the U.S., Europe, Japan and other Asian countries through our pharmaceutical company relationships.

We have a pipeline of other products at various stages of development and approval. We are currently conducting clinical studies of VIBEX® QS T, for testosterone replacement therapy, and on February 25, 2015, we announced positive top-line pharmacokinetic results that showed that the primary endpoint was achieved in the Company's ongoing, multi-center, phase 3 clinical study (QST-13-003) evaluating the efficacy and safety of testosterone enanthate administered once-weekly by subcutaneous injection using the QuickShot® auto injector in testosterone deficient adult males. We have also initiated manufacturing development work for QS M, a combination product for an undisclosed central nervous system ("CNS") indication.

Our development projects in collaboration with Teva include VIBEX® Epinephrine, an exenatide multi-dose pen, and another undisclosed multi-dose pen. In December 2014, Teva submitted the final amendment to the VIBEX® Epinephrine Pen ANDA, and FDA accepted Teva's filing of an ANDA in October 2014 for exenatide, formerly referred to as Teva "Pen 2". We are also developing VIBEX® Sumatriptan for the acute treatment of migraines, which if approved, will be sold by Teva. In January 2015, we received a complete response letter from FDA regarding our Abbreviated New Drug Application ("ANDA") for VIBEX® Sumatriptan, providing revisions to labelling and citing minor deficiencies, and we submitted our response to FDA in March 2015. We received a second complete response letter from the FDA, primarily requesting additional labeling revisions, and submitted our response in July 2015. We have begun commercial scale tooling and mold fabrication in anticipation of potential approval and launch.

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

## Results of Operations

We reported a net loss of \$5,738,041 and \$14,032,361 for the three and nine month periods ended September 30, 2015, respectively. Operating results for the three and nine months ended September 30, 2015 are not necessarily indicative of the results that may be expected for the year ending December 31, 2015. The following is an analysis and discussion of our operations for the three and nine months ended September 30, 2015 as compared to the same periods in 2014.

## Revenues

|   | Three Months Ended September 30, |              | Nine Months Ended September 30, |               |
|---|----------------------------------|--------------|---------------------------------|---------------|
|   | 2015                             | 2014         | 2015                            | 2014          |
| OTREXUP™                                    | \$ 3,592,779                     | \$ 2,606,973 | \$ 9,943,182                    | \$ 4,491,288  |
| Needle-free injector devices and components | 1,193,813                        | 653,842      | 3,339,548                       | 3,598,846     |
| Auto injector and pen injector devices      | 3,240,437                        | 298,764      | 5,207,463                       | 634,750       |
| Total product sales                         | 8,027,029                        | 3,559,579    | 18,490,193                      | 8,724,884     |
| Development revenue                         | 2,608,336                        | 1,744,735    | 8,024,184                       | 4,954,285     |
| Licensing revenue                           | 42,960                           | 926,955      | 6,112,341                       | 2,783,434     |
| Royalties                                   | 407,427                          | 339,312      | 1,227,462                       | 1,636,958     |
| Total revenue                               | \$ 11,085,752                    | \$ 6,570,581 | \$ 33,854,180                   | \$ 18,099,561 |

Total revenues for the three and nine month periods ended September 30, 2015 grew to \$11,085,752 and \$33,854,180, respectively, as compared to \$6,570,581 and \$18,099,561 for the three and nine month periods ended September 30, 2014, respectively, representing an overall growth in total revenue of 69% and 87% for the three and nine month periods, respectively, as compared to the same periods in the prior year. Below is a detailed discussion of the components of revenue.

#### OTREXUP™

In 2014, we began recognizing OTREXUP™ product revenue. We began detailing OTREXUP™ to rheumatologists in February 2014, and LEO Pharma began detailing to dermatologists in March 2014. In June 2015, our license and promotion arrangement with LEO was terminated and we regained the exclusive rights to market OTREXUP™ in the U.S. We sell OTREXUP™ in a package of four pre-filled, single-dose disposable auto injectors to wholesale pharmaceutical distributors, our customers. Sales to our customers are subject to specified rights of return. We currently defer recognition of revenue on product shipments of OTREXUP™ to our customers until the right of return no longer exists, which occurs at the earlier of the time OTREXUP™ units are dispensed through patient prescriptions or expiration of the right of return.

For the three and nine month periods ended September 30, 2015, we recognized \$3,592,779 and \$9,943,182, respectively, related to the sale of our product OTREXUP™ based on prescription data. Sales of OTREXUP™ increased \$985,806, or 38%, and \$5,451,894, or 121% for the quarter and nine month periods ended September 30, 2015, respectively, as compared with sales in the same periods in 2014. We believe the increase in sales is a direct result of an increase in our sales force and marketing efforts.

We had deferred revenue of \$954,401 and \$1,061,947 at September 30, 2015 and December 31, 2014, respectively, for OTREXUP™ product shipments to wholesalers, which is net of product sales allowances. We will continue to recognize revenue upon the earlier to occur of prescription units dispensed or expiration of the right of return until we can reliably estimate product returns, at which time we will record a one-time increase in net revenue related to the recognition of revenue previously deferred.

#### Needle-free injector devices and components

Our revenues from reusable needle-free injector devices and disposable components totaled \$1,193,813 and \$3,339,548 for the three and nine months ended September 30, 2015, respectively, as compared to \$653,842 and \$3,598,846 for the three and nine month periods ended September 30, 2014, respectively. These revenues are generated primarily from sales to Ferring, which uses our needle-free injector with their 4 mg and 10 mg hGH formulations marketed as Zomajet® 2 Vision and Zomajet® Vision X, respectively, in Europe and Asia. Previously, Teva used our Tjet® needle-free device with their 5 mg hGH Tev-Tropin® marketed in the U.S. In April 2014, Teva initiated a recall of the drug product, Tev-Tropin® (not the device which we supply) and had halted sales of the drug earlier that year, which had a negative effect on the level of our product sales to Teva. In the fourth quarter of 2014, Ferring purchased the U.S. rights to Tev-Tropin® from Teva. In March 2015, Ferring received FDA approval of a name change enabling its newly acquired recombinant human growth hormone to be marketed in the U.S. as ZOMACTON™ (somatotropin [rDNA origin]) for injection, and the needle-free delivery system to be marketed in the U.S. as ZOMA-Jet™. Also in March 2015, Ferring received approval from the FDA to market the 10 mg needle free injector device. Ferring launched ZOMACTON™ in the U.S. in the second quarter of 2015 and the ZOMA-Jet™ needle-free devices are expected to be available later in 2015. However, we do not control our partners' inventory levels of our hGH injectors or disposable components, which can cause significant fluctuations in product sales.

#### Auto injector and pen injector devices

Product sales from auto injector and pen injector devices totaled \$3,240,437 and \$5,207,463 for the three and nine months ended September 30, 2015, principally attributable to shipments of auto injectors to Teva for use with their generic epinephrine product in anticipation of a possible launch. Amounts recognized in the nine month periods ended September 30, 2015 and 2014 also included sales of approximately \$198,000 and \$515,000, respectively, of pre-commercial pen injector devices sold to Teva for use with an undisclosed product (Pen 1).

#### Development revenue

Development revenues typically represent amounts earned under arrangements with partners for which we develop new products on their behalf. Frequently, we receive payments from our partners that are initially deferred and recognized as revenue over a development period or upon completion of defined deliverables. Development revenue totaled \$8,024,184 and \$4,954,285 for the nine months ended September 30, 2015 and 2014, respectively and \$2,608,336 and \$1,744,735 for the three month periods ended September 30, 2015 and 2014, respectively. The development revenue for each period presented was primarily related to the Teva auto injector and pen injector programs.

#### Licensing Revenue



Licensing revenue represents amounts recognized in connection with up-front or milestone payments received from partners that are initially deferred and recognized over the estimated term of the agreement. We recognized \$42,960 and \$6,112,341 for the three and nine months ended September 30, 2015, respectively as compared with \$926,955 and \$2,783,434 for the three and nine month periods and September 30, 2014, respectively. The licensing revenue recognized for the periods in 2014 and through the second quarter of 2015 was primarily attributable to our license and promotion agreement with LEO Pharma, which began in November of 2013. The upfront and milestone payments received from LEO totaling \$10.0 million were being recognized into revenue over a 35-month period. As discussed above, and in Note 3 to the Consolidated Financial Statements, the agreement with LEO Pharma was terminated effective June 23, 2015. As a result of the termination of the agreement, we recognized the remaining unamortized balance of the deferred revenue of \$5,142,857 as licensing revenue in the second quarter of 2015. No revenue related to this arrangement was recognized in the third quarter of 2015 and we do not expect to recognize any additional revenue related to this agreement in future periods.

## Royalties

Royalty revenue totaled \$407,427 and \$1,227,462 for the three and nine month periods ended September 30, 2015 as compared to \$339,312 and \$1,636,958 for the three and nine month periods ended September 30, 2014, respectively. We receive royalties from Ferring related to needle-free injector device sales, from Meda Pharmaceuticals, Inc. on sales of Elestrin<sup>®</sup> and from Actavis plc on sales of Gelnique 3%<sup>®</sup>. In 2014, we also received royalties from Teva for hGH sales. The overall decrease in royalty revenue in the nine month period in 2015 compared to 2014 was primarily the result of receiving no royalties from Teva after the first quarter of 2014. Our royalties from Teva were based on Teva's sales of their hGH drug, Tev-Tropin<sup>®</sup>. Teva initiated a recall of the drug product, Tev-Tropin<sup>®</sup> (not the device which we supply), at the end of April 2014 and had halted sales of the drug earlier in the year. In the fourth quarter of 2014, Ferring purchased the U.S. rights to Tev-Tropin<sup>®</sup> from Teva. In March 2015, Ferring received FDA approval of a name change enabling its newly acquired recombinant human growth hormone to be marketed in the U.S. as ZOMACTON<sup>™</sup>(somatropin [rDNA origin]) for injection, and the needle-free delivery system to be marketed in the U.S. as ZOMA-Jet<sup>™</sup>. Also in March 2015, Ferring received approval from the FDA to market the 10 mg needle free injector device. Ferring launched ZOMACTON<sup>™</sup> in the U.S. in the second quarter of 2015 and the ZOMA-Jet<sup>™</sup> needle-free devices are expected to be available in late 2015 or early 2016.

## Cost of Revenue and Gross Profit

The following table summarizes our total cost of revenue and gross profit:

|                         | Three Months Ended September 30, |              | Nine Months Ended September 30, |               |
|-------------------------|----------------------------------|--------------|---------------------------------|---------------|
|                         | 2015                             | 2014         | 2015                            | 2014          |
| Total revenue           | \$ 11,085,752                    | \$ 6,570,581 | \$ 33,854,180                   | \$ 18,099,561 |
| Total cost of revenue   | 5,099,763                        | 2,507,366    | 13,482,586                      | 5,814,191     |
| Gross profit            | \$ 5,985,989                     | \$ 4,063,215 | \$ 20,371,594                   | \$ 12,285,370 |
| Gross profit percentage | 54                               | % 62         | % 60                            | % 68          |

Our gross profit rose to \$5,985,989 and \$20,371,594 for the three and nine month periods ended September 30, 2015, respectively, representing an increase of 47% and 66%, respectively, as compared to the same periods in the previous year. Overall, the significant increase in our revenues and gross profit is primarily attributable to licensing revenue recognized in connection with the termination of our agreement with LEO, along with the increase in sales of our product OTREXUP<sup>™</sup>, which was launched in February 2014. Other variations in revenue, cost of revenue and gross profit are attributable to our development activities, which fluctuate depending on the mix of development projects in progress and stages of completion in each period, as discussed in more detail below.

The following table summarizes the revenue, cost of sales and gross margin associated with our product sales:

|                       | Three Months Ended September 30, |              | Nine Months Ended September 30, |              |
|-----------------------|----------------------------------|--------------|---------------------------------|--------------|
|                       | 2015                             | 2014         | 2015                            | 2014         |
| Product sales         | \$ 8,027,029                     | \$ 3,559,579 | \$ 18,490,193                   | \$ 8,724,884 |
| Cost of product sales | 3,265,983                        | 2,158,266    | 7,763,734                       | 5,021,896    |
| Product gross margin  | \$ 4,761,046                     | \$ 1,401,313 | \$ 10,726,459                   | \$ 3,702,988 |

Gross margin percentage 59 % 39 % 58 % 42 %

The cost of product sales includes product acquisition costs from third-party manufacturers and internal manufacturing overhead expenses. The product gross margin increase in the three and nine month periods in 2015 compared to 2014 was the result of an increase in sales of OTREXUP™, which generates a higher gross margin than our other products.

The cost of development revenue consists primarily of direct external costs, some of which may have been previously incurred and deferred. The cost of development revenue in each period was primarily related to revenue recognized under the Teva auto injector and pen injector programs. Development gross profits can vary significantly from period to period depending on the mix of development projects in progress and stages of completion in each period.

#### Research and Development

Research and development expenses consist of external costs for studies and analysis activities, design work and prototype development, FDA fees, personnel costs and other general operating expenses associated with research and development. Research and development expenses totaled \$5,142,387 and \$14,089,100 for the three and nine month periods ended September 30, 2015, respectively as compared to \$4,426,730 and \$12,903,304 incurred in the same periods in the prior year. The increase in research and

development expenses was attributable primarily to additional FDA fees and personnel costs incurred in the three and nine month periods ended September 30, 2015, respectively, as compared to the same periods in 2014.

#### Selling, General and Administrative

Selling, general and administrative expenses were relatively consistent at \$6,611,169 and \$6,810,089 for the three month periods ended September 30, 2015 and 2014, respectively. Total selling, general and administrative expenses for the nine months ended September 30, 2015 and 2014 were \$20,253,489 and \$24,455,167, respectively. The decrease for the nine month periods was primarily due to a reduction in expenses related to OTREXUP™ market research, product branding, commercialization and pre-commercialization activities as well as a reduction in litigation fees incurred in the prior year in connection with litigation settled in early 2015.

#### Liquidity and Capital Resources

At September 30, 2015, our cash and short-term investments totaled \$47.9 million, which consisted of \$35.9 million in cash and \$12.0 million in short-term investments. We also held long-term investments totaling \$3.0 million as of September 30, 2015. All investments are U.S. Treasury bills or U.S. Treasury notes which we intend to hold to maturity.

On May 11, 2015, we completed an underwritten offering of 23,000,000 shares of our common stock at a price to the public of \$2.00 per share. We received net proceeds of approximately \$42.9 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from the offering for general corporate purposes including business development, in-licensing and acquisitions.

We believe that the combination of our current cash and investments balances and projected product sales, product development, license revenues, milestone payments and royalties will provide us with sufficient funds to support operations. We do not currently have any bank credit lines. If in the future we do not turn profitable or generate cash from operations as anticipated and additional capital is needed to support operations, we may raise additional funds through public or private equity offerings, debt financings or from other sources. We may be unable to obtain such financing, or obtain it on favorable terms, in which case we may be required to curtail development of new products, limit expansion of operations or accept financing terms that are not as attractive as we may desire.

#### Cash Flows

##### Net Cash Used in Operating Activities

Operating cash inflows are generated primarily from product sales, license and development fees and royalties. Operating cash outflows consist principally of expenditures for manufacturing costs, general and administrative costs, research and development projects including clinical studies, and sales and marketing activities. Fluctuations in cash used in operating activities are primarily a result of the timing of cash receipts and disbursement. Net cash used in operating activities was \$25,850,595 for the nine months ended September 30, 2015 as compared to \$20,477,611 for the nine months ended September 30, 2014. The increase in cash used in operating activities is primarily the result of additional cash used to pay down accounts payable in the second and third quarters of 2015 as compared to 2014, combined with a growth in accounts receivable and a reduction in deferred revenue related to cash payments received from LEO and Teva in prior periods that were recognized in income in 2015.

##### Net Cash Provided by (Used in) Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2015 was \$15,059,050 as compared to net cash provided by investing activities of \$17,708,319 for the nine months ended September 30, 2014. The change is primarily attributable to timing of purchases and maturities of investment securities as well as timing and amount of capital expenditures. In the first nine months of 2014, we received \$21,000,000 in connection with the maturities of investments as compared to a net cash outflow of \$9,037,675 towards the purchase of investments in the first nine months of 2015. The remaining change is due to an increased use of cash for purchases of equipment, molds, furniture and fixtures, primarily related to VIBEX® QS T and VIBEX® Sumatriptan commercial molds and assembly equipment, and capitalized patent costs.

#### Net Cash Provided by Financing Activities

Net cash provided by financing activities in the first nine months of 2015 totaled \$42,762,907, and was principally attributable to proceeds received in connection with our underwritten offering of common stock which resulted in net proceeds to us of \$42,850,677 after underwriting discounts and expenses payable by us. The net cash provided by financing activities in the first nine months of

2014 totaled \$2,754,143 and consisted primarily of \$2,908,540 cash proceeds received from the exercise of 545,100 warrants and 1,991,728 options during the period. There were no options or warrants exercised in the first nine months of 2015.

#### Research and Development Programs

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

VIBEX® QS T. We are developing VIBEX® QS T for self-administered weekly injections of testosterone enanthate in a preservative free formulation for men requiring testosterone replacement. The VIBEX® QS T injector is based on our VIBEX® QS auto injector system which offers a dose capacity of 1 mL in a compact design. VIBEX® QS is designed to enhance performance on the attributes most critical to patient acceptance - speed, comfort and discretion. We believe VIBEX® QS achieves these advancements by incorporating a novel triggering mechanism and space-saving spring configuration. The design also accommodates fast injection of highly-viscous drug products, such as testosterone, that stall less-powerful conventional auto injectors.

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

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

On February 25, 2015, we announced positive top-line pharmacokinetic results that showed that the primary endpoint was achieved in QST-13-003. The protocol for the study required that at the week 12 endpoint: (i) at least 75% of all patients'  $C_{avg}$  are within the normal range of 300 to 1100 ng/dL, with a lower limit of a 95% 2-sided confidence interval of greater than or equal to 65%, (ii) at least 85% of patients'  $C_{max}$  are less than 1500 ng/dL and (iii) no more than 5% of patients had a  $C_{max}$  greater than 1800 ng/dL. The primary endpoint of the population that received one or more doses of QS T was met by 139 out of 150 patients, equating to 92.7% with a 95% confidence interval of 87.3% to 96.3%. Among the 137 patients that completed all 12 weeks of dosing and PK sampling, 98.5% were within the pre-defined range. The top-line results are summarized in the table below.

| Population/Analysis | $C_{avg}$ Lower | $C_{avg}$ % in range | $C_{max}$ <1500 |
|---------------------|-----------------|----------------------|-----------------|
|---------------------|-----------------|----------------------|-----------------|

|                            | limit of the | 300 – 1100 ng/dL | ng/dL        | $C_{max}$<br>>1800 |
|----------------------------|--------------|------------------|--------------|--------------------|
| 95% 2-sided                | n (%)        |                  | n (%)        | ng/dL              |
| C. I.                      |              |                  |              | n (%)              |
| Primary analysis* N=150    | 87.3         | % 139 (92.7      | %) 137 (91.3 | %)** 0 %           |
| Completers N=137           | 94.8         | % 135 (98.5      | %) 137 (100  | %) 0 %             |
| Protocol-Required Outcomes | ≥65          | % 75             | % ≥85        | % ≤5 %             |

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

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

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

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

After we initiated study QST-13-003, but before we announced positive top-line pharmacokinetic results in February 2015, we received written recommendations from the FDA related to our clinical development program for QS T. The recommendations received were in response to various clinical, Chemistry, Manufacturing and Controls and user study submissions that we made through November 2014. We believe that we had already factored many of the recommendations cited in the advice letter into the protocol of the ongoing QST-13-003 study and into the protocols for planned human use studies as a result of guidance provided by the FDA at the May 2014 Type C meeting. Based on a single reported occurrence of hives in our phase II study, which the FDA characterized as an apparent allergic reaction, as well as the known safety experience with other parenteral testosterone products, the FDA recommended that we create a larger safety database, including approximately 350 subjects exposed to QS T with approximately 200 subjects exposed for six months and approximately 100 subjects exposed for a year. Based on the number of subjects in previous studies and in the current QST-13-003 study, we concluded that we would need additional subjects exposed to QS T for six months. We assessed the FDA's comments in the advice letter and their impact on the timing of the filing of a New Drug Application ("NDA") for QS T with the FDA. The timing and design of the study to obtain the additional subjects and data required was determined based on further discussion with the FDA. We submitted our response to the FDA's written recommendations in early March 2015.

In May 2015, we received a written update from the FDA related to our clinical development program for QS T. We believe, based on the update received from the FDA, there is an agreed upon path forward for the completion of an additional study to support the filing of a New Drug Application for QS T. In June 2015, we finalized and submitted the protocol for the study, and in August 2015, we enrolled the first patients in the study, which is known as QST-15-005. The study includes a screening phase, a treatment titration phase and a treatment phase for evaluation of safety and tolerability assessments, including laboratory assessments, adverse events and injection site assessments. The study is a dose-blind, multiple-dose, concentration controlled 26-week supplemental safety and pharmacokinetic study of QuickShot® Testosterone. Patients meeting all eligibility criteria will be assigned to receive 75 mg of QS T once weekly for six weeks. According to the protocol, adjustments to dose may be made at week seven based upon the week six  $C_{trough}$  value. QS T will be provided to clinical sites at dosage strengths of 100 mg, 75 mg and 50 mg to be utilized in dose titration.

In October 2015, we announced that the last patient in study QST-13-003 received their week 52 treatment, which marks the end of the treatment and follow up phase of this study. In early November 2015, the Company also announced that enrollment was complete in study QST-15-005. At that time, 108 patients had received a dose of QS T. Following completion of screening, the Company estimated the total number of dosed patients would be approximately 125. The Company believes that upon successful completion of this study we should be able to meet the FDA's recommendation for the larger safety database as discussed above. We anticipate the last patient in the study will complete their final visit in the second quarter of 2016.

**Device Development Projects.** We are also engaged in research and development activities related to our VIBEX® disposable pressure-assisted auto injectors and our disposable pen injectors. We have signed license agreements with Teva for our VIBEX® system for use with epinephrine and sumatriptan and for our pen injector device for use with exenatide and one undisclosed product. Our pressure-assisted auto injectors are designed to deliver drugs by injection from single-dose prefilled syringes. The auto injectors are in the advanced commercial stage of development. The disposable pen injector device is designed to deliver drugs by injection through needles from multi-dose cartridges. The disposable pen is entering the commercial stage of development. Our development programs consist of the determination of the device design, development of prototype tooling, production of prototype devices for testing and clinical studies, performance of clinical studies, and development of commercial tooling and assembly.

The development timelines of the auto and pen injectors related to the Teva products are controlled by Teva. We expect development related to the Teva products to continue in 2015, but the timing and extent of near-term future development will be dependent on certain decisions made by Teva. Although development work payments and



certain upfront and milestone payments have been received from Teva, there have been no commercial sales by Teva from the auto injector or pen injector programs, timelines have been extended and there can be no assurance that there ever will be commercial sales or future milestone payments under these agreements.

**Other Research and Development Costs.** In addition to the VIBEX® QS T project and the Teva-related device development projects, we incur direct costs in connection with other research and development projects related to our technologies and indirect costs that include personnel costs, administrative and other operating costs related to managing our research and development projects.

#### Subsequent Event

In December 2011, we entered into a licensing agreement (the “Agreement”) with Pfizer Consumer Healthcare (“Pfizer”) for one of our drug delivery technologies to develop an undisclosed product on an exclusive basis for North America. On October 5, 2015, we received a written notice of termination of the Agreement from Pfizer. Pfizer informed us that the product Pfizer was developing failed to meet pre-specified endpoints in a clinical study, and accordingly, the Agreement will terminate on November 5, 2015.

#### Off-Balance Sheet Arrangements

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

#### Critical Accounting Policies

We have identified certain of our significant accounting policies that we consider particularly important to the portrayal of our results of operations and financial position and which may require the application of a higher level of judgment by management and, as a result, are subject to an inherent level of uncertainty. These policies are characterized as “critical accounting policies” and address revenue recognition and valuation of long-lived and intangible assets and goodwill, as more fully described under “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the year ended December 31, 2014.

#### Recently Issued Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update (“ASU”) No. 2014-09, Revenue from Contracts with Customers, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The ASU will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The standard creates a five-step model that requires a company to: identify customer contracts, identify the separate performance obligations, determine the transaction price, allocate the transaction price to the separate performance obligations and recognize revenue when each performance obligation is satisfied. Applying the standard requires a company to exercise judgment when considering the terms of the contracts and all relevant facts and circumstances. In August 2015, the FASB issued ASU No. 2015-14 which defers the effective date of ASU No. 2014-09 by one year to annual reporting periods beginning after December 15, 2017, including interim periods within that year. The standard allows for either full retrospective adoption, where the standard is applied to all periods presented, or modified retrospective adoption where the standard is applied only to the most current period presented in the financial statements. Early adoption of ASU 2014-09 is permitted but not before the original effective date (annual periods beginning after December 15, 2016). We are currently evaluating the impact of the adoption of this revenue standard on our consolidated results of operations and financial position and have not yet selected a transition date or method.

In July 2015, the FASB issued ASU No. 2015-11, Simplifying the Measurement of Inventory. The new standard changes the measurement principle for inventory from the lower of cost or market to lower of cost and net realizable value. The standard is effective for public entities for annual and interim periods beginning after December 15, 2016. Early adoption is permitted. Entities are required to disclose the nature and reason for the change in accounting principle in the first interim and annual period of adoption. We are currently evaluating the effect, if any, this standard will have on our consolidated results of operations and financial position.

#### 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

periods ended September 30, 2015 was not material.

We also have limited exposure to market risk due to interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because a significant portion of our investments are in debt securities issued by the U.S. government and institutional money market funds. The primary objective of our investment activities is to preserve principal. To minimize market risk, we have in the past and, to the extent possible, will continue in the future, to hold debt securities to maturity at which time the debt security will be redeemed at its stated or face value. Due to the nature of our marketable securities, we believe that we are not exposed to any material market interest rate risk related to our investment portfolio.

23

---

#### Item 4. CONTROLS AND PROCEDURES

##### Disclosure Controls and Procedures

The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this report. The evaluation was performed to determine whether the Company's disclosure controls and procedures have been designed and are functioning effectively to provide reasonable assurance that the information required to be disclosed by the Company in reports filed under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and is accumulated and communicated to management, including the Company's principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Based on such evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures as of the end of the period covered by this report were effective.

##### Internal Control over Financial Reporting

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

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

## PART II - OTHER INFORMATION

### Item 1A. RISK FACTORS

In addition to the other information contained in this report, you should carefully consider the risk factors discussed in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2014, which could materially affect our business, financial condition or future results. There have been no material changes to these risk factors. The risks described in our Annual Report on Form 10-K are not the only risks facing us. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

Item 6. EXHIBITS

(a) Exhibit Index

| Exhibit No. | Description   |
|-------------|---|
| 10.1        | Separation and Consulting Services Agreement dated July 13, 2015, by and between Antares Pharma, Inc. and Jennifer Evans Stacey (Filed as Exhibit 99.1 to Form 8-K filed on July 16, 2015, and incorporated herein by reference.) |
| 10.2        | Employment Agreement dated as of July 8, 2015 between Antares Pharma, Inc. and Peter J. Graham (Filed as Exhibit 10.2 to Form 10-Q filed on August 10, 2015, and incorporated herein by reference.)                               |
| 31.1#       | Certificate of the Chief Executive Officer of Antares Pharma, Inc. required by Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended.  |
| 31.2#       | Certificate of the Chief Financial Officer of Antares Pharma, Inc. required by Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended.  |
| 32.1##      | Certificate of the Chief Executive Officer of Antares Pharma, Inc. required by Rule 13a-14(b) under the Securities Exchange Act of 1934, as amended.  |
| 32.2##      | Certificate of the Chief Financial Officer of Antares Pharma, Inc. required by Rule 13a-14(b) under the Securities Exchange Act of 1934, as amended.  |
| 101.INS#    | XBRL Instance Document  |
| 101.SCH#    | XBRL Taxonomy Extension Schema Document   |
| 101.CAL#    | XBRL Taxonomy Extension Calculation Linkbase Document   |
| 101.LAB#    | XBRL Taxonomy Extension Label Linkbase Document   |
| 101.PRE#    | XBRL Taxonomy Extension Presentation Linkbase Document  |
| 101.DEF#    | XBRL Taxonomy Extension Definition Document   |
| #           | Filed herewith.   |
| ##          | Furnished herewith.   |

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 5, 2015 /s/ Eamonn Hobbs  
Eamonn Hobbs  
President and Chief Executive Officer  
(Principal Executive Officer)

November 5, 2015 /s/ James E. Fickenscher  
James E. Fickenscher  
Senior Vice President and Chief Financial Officer  
(Principal Financial and Accounting Officer)