ANTARES PHARMA, INC.
Form 10-Q
August 12, 2010

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

_____

FORM 10-Q

_____

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the quarterly period ended June 30, 2010

Commission File Number 1-32302

ANTARES PHARMA, INC.

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, 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 o No o

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.

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

The number of shares outstanding of the registrant's Common Stock, $.01 par value, as of August 11, 2010, was 83,547,968.

ANTARES PHARMA, INC.

INDEX

PART I - FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS.

ANTARES PHARMA, INC.
CONSOLIDATED BALANCE SHEETS

See accompanying notes to consolidated financial statements.

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

See accompanying notes to consolidated financial statements.

ANTARES PHARMA, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)

See accompanying notes to consolidated financial statements

ANTARES PHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

1. Description of Business

Antares Pharma, Inc. (the "Company" or "Antares") is an emerging pharma company that focuses on self-injection pharmaceutical products and technologies and topical gel-based products. The Company's subcutaneous and intramuscular injection technology platforms include Vibex disposable pressure-assisted auto injectors, Vision reusable needle-free injectors, and disposable multi-use pen injectors. Pharmaceutical and biotechnology companies are viewed as the Company's primary customers.

In the injector area, the Company has licensed its reusable needle-free injection device for use with human growth hormone ("hGH") to Teva Pharmaceutical Industries, Ltd. ("Teva"), Ferring Pharmaceuticals BV ("Ferring") and JCR Pharmaceuticals Co., Ltd. ("JCR"). In August 2009, the Company announced that Teva launched its Tjet® injector system, which uses the Company's needle-free device to administer Teva's Tev-Tropin® brand hGH. The Company has also licensed both disposable auto and pen injection devices to Teva for use in certain fields and territories. In 2009, the Company received a payment of $4,076,375 from Teva for tooling and for an advance for the design, development and purchase of additional tooling and automation equipment, all of which is related to a fixed, single-dose, disposable injector product containing epinephrine using the Company's Vibex auto injector platform. In addition, the Company continues to support existing customers of its reusable needle-free devices for the home or alternate site administration of insulin in the U.S. market through distributors.

In the gel-based area, the Company recently completed a pivotal Phase 3 trial for its lead product candidate, Anturol®, an oxybutynin ATD gel for the treatment of overactive bladder ("OAB"), for which the Company expects to file a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") in 2010. The Company also has a partnership with BioSante Pharmaceuticals, Inc. ("BioSante") that includes LibiGel® (transdermal testosterone gel) in Phase 3 clinical development for the treatment of female sexual dysfunction ("FSD"), and Elestrin® (estradiol gel) currently marketed in the U.S. for the treatment of moderate-to-severe vasomotor symptoms associated with menopause.

The Company has operating facilities in the U.S. and Switzerland. The U.S. operation manufactures and markets the Company's reusable needle-free injection devices and related disposables, and develops its disposable pressure-assisted auto injector and pen injector systems. These operations, including all development and some U.S. administrative activities, are located in Minneapolis, Minnesota. The Company's Pharma division is located both in the U.S. and in Muttenz, Switzerland, where pharmaceutical products are developed utilizing the Company's transdermal systems. The Company's corporate offices are located in Ewing, New Jersey.

2. Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United State of America for interim financial information and with the instructions to Form 10-Q and Article 10 of the Securities and Exchange Commission's Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. The accompanying consolidated financial statements and notes should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended December 31, 2009. Operating results for the three and six-month periods ended June 30, 2010 are not necessarily indicative of the results that may be expected for the year ending December 31, 2010.

3. Stockholders' Equity

Common Stock

Warrant and stock option exercises in the first six months of 2010 and 2009 resulted in proceeds of $1,692,826 and $53,667, respectively, and in the issuance of 1,531,101 and 85,333 shares of common stock, respectively.

Stock Options and Warrants

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

The Company's 2008 Equity Compensation Plan (the "Plan") allows for the grants of options, restricted stock, stock units, stock appreciation rights and/or performance awards to officers, directors, consultants and employees. Under the Plan, the maximum number of shares of stock that may be granted to any one participant during a calendar year is 1,000,000 shares. Options to purchase shares of common stock are granted at exercise prices not less than 100% of the fair market value on the dates of grant. The term of the options range from three to eleven years and they vest in varying periods. In May 2010, the shareholders approved an amendment to the Plan to increase the maximum number of shares authorized for issuance by 1,500,000 to 11,500,000 from 10,000,000. As of June 30, 2010, the Plan had 2,024,022 shares available for grant. The number of shares available for grant does not take into consideration potential stock awards that could result in the issuance of shares of common stock if certain performance conditions are met, as discussed under "Stock Awards" below. Stock option exercises are satisfied through the issuance of new shares.

A summary of stock option activity under the Plan as of June 30, 2010, and the changes during the six-month period then ended is as follows:

During the first six months of 2010, the Company granted options to purchase a total of 552,487 shares of its common stock at exercise prices ranging from $1.30 to $1.60. During the first six months of 2009, the Company granted options to purchase a total of 406,927 shares of its common stock at exercise prices ranging from $0.47 to $0.53. All options were granted at exercise prices which equaled the fair value of the Company's common stock on the dates of the grants.

Total recognized compensation expense for stock options was approximately $446,100 and $466,000 for the first six months of 2010 and 2009, respectively. As of June 30, 2010, there was approximately $1,011,100 of total unrecognized compensation cost related to nonvested outstanding stock options that is expected to be recognized over a weighted average period of approximately 1.6 years.

The per share weighted average fair value of options granted during the first six months of 2010 and 2009 were estimated as $0.79 and $0.36, 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.

Warrants to purchase a total of 18,019,159 shares of common stock were outstanding at June 30, 2010. The weighted average exercise price of the warrants was $1.56.

The weighted average exercise price of the stock options and warrants outstanding at June 30, 2010 and 2009 was $1.44 and $1.57, respectively.

Stock Awards

The employment agreements with the Chief Executive Officer, Chief Financial Officer and other members of executive management include stock-based incentives under which the executives could be awarded up to approximately 1,530,000 shares of common stock upon the occurrence of various triggering events. Of these shares, 45,454 were awarded in the first half of

2010 and 180,681 were awarded prior to 2010. A total of approximately $18,200 of compensation expense was recorded in the first half of 2010 in connection with awards considered probable of achievement.

A total of 435,768 shares of common stock have been granted as stock awards to members of management, of which 170,768 were granted in the first half of 2010. The majority of the stock awards vest over a three-year period, although 25,000 shares granted in the first quarter of 2010 vested immediately. A total of 239,104 of the shares granted are unvested as of June 30, 2010. Expense is recognized on a straight-line basis over the vesting period and is based on the fair value of the stock on the grant date. The fair value of each stock award is determined based on the number of shares granted and the market price of the Company's common stock on the date of grant. Expense recognized in connection with these awards was approximately $85,000 and $25,000 in the first six months of 2010 and 2009, respectively. The weighted average fair value of the shares granted in 2010 was $1.30 per share.

4. Net Loss Per Share

Basic loss per common share is computed by dividing net loss applicable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted loss per common share reflects the potential dilution from the exercise or conversion of securities into common stock. Potentially dilutive stock options and warrants excluded from dilutive loss per share because of their effect was anti-dilutive totaled 25,404,379 and 20,865,477 at June 30, 2010 and 2009, respectively. The table below discloses the basic and diluted loss per common share.

5. Industry Segment and Operations by Geographic Areas

The Company has one operating segment, drug delivery, which includes the development of drug delivery transdermal products and drug delivery injection devices and supplies.

The geographic distributions of the Company's identifiable assets and revenues are summarized in the following tables:

The Company has assets located in two countries as follows:

Revenues by customer location are summarized as follows:

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

6. Comprehensive Loss

7. Revenue Recognition Change

In the third quarter of 2009, the Company elected early adoption of Financial Accounting Standards Board ("FASB") Accounting Standards Update ("ASU") 2009-13, "Revenue Arrangements with Multiple Deliverables" ("ASU 2009-13"). ASU 2009-13, which amended FASB ASC 605-25, "Multiple-Element Arrangements," is effective for arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, but allows for early adoption. ASU 2009-13 requires a vendor to allocate revenue to each unit of accounting in arrangements involving multiple deliverables. It changes the level of evidence of standalone selling price required to separate deliverables by allowing a vendor to make its best estimate of the standalone selling price of deliverables when vendor specific objective evidence or third party evidence of selling price is not available. As a result of adoption of ASU 2009-13, deferred revenues and deferred costs associated with one License, Development and Supply Agreement with Teva will be recognized as revenues and expenses earlier than would otherwise have occurred. Adoption of ASU 2009-13 had no impact on the accounting for any of the Company's other revenue arrangements containing multiple deliverables. Revenues and expenses generated in connection with future multiple element arrangements will likely often be recognized over shorter periods than would have occurred prior to adoption of ASU 2009-13.

The Company elected to adopt ASU 2009-13 on a prospective basis, with retrospective application to January 1, 2009. Because ASU 2009-13 was adopted in the third quarter of 2009, the amounts reported in the first and second quarters of 2009 are required to be adjusted and reported as if adoption occurred on January 1, 2009.

The tables below reconcile the amounts for the three months and six months ended June 30, 2009 as previously reported to the amounts as reported in the consolidated statement of operations after applying adjustments reflecting adoption of ASU 2009-13 on a prospective basis with retrospective application to January 1, 2009.

8. New Accounting Pronouncements

In April 2010, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2010-17 (ASU 2010-17), Revenue Recognition Milestone Method (Topic 605), which provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. Research or development arrangements frequently include payment provisions whereby a portion or all of the consideration is contingent upon milestone events such as successful completion of phases in a study or achieving a specific result from the research or development efforts. The amendments in this ASU provide guidance on the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. ASU 2010-17 is effective for fiscal years and interim periods within those years beginning on or after June 15, 2010, with early adoption permitted. This ASU is effective for the Company on January 1, 2011. The Company is currently evaluating the impact, if any, ASU 2010-17 will have on the Company's consolidated financial statements.

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

Forward-Looking Statements

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

- the impact of new accounting pronouncements;
- our expectations regarding product development, manufacturing and partnering of Anturol®;
- our expectations regarding continued product development with Teva;
- our plans regarding potential manufacturing and marketing partners;
- our future cash flow;
- our expectations regarding a net loss for the year ending December 31, 2010; and
- our ability to raise additional financing, reduce expenses or generate funds in light of our current and projected level of operations and general economic conditions.

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

- our inability to compete successfully against new and existing competitors or to leverage our marketing capabilities and our research and development capabilities;
- our ability to partner Anturol®;
- delays in product introduction and marketing or interruptions in supply;
- a decrease in business from our major customers and partners;
- adverse economic and political conditions;
- our inability to obtain additional financing, reduce expenses or generate funds when necessary;

- our inability to attract and retain key personnel; and

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

In addition, you should refer to the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2009 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. is an emerging pharma company that focuses on self-injection pharmaceutical products and technologies and topical gel-based products. Our subcutaneous and intramuscular injection technology platforms include Vibex disposable pressure-assisted auto injectors, Vision reusable needle-free injectors and disposable multi-use pen injectors. We currently view pharmaceutical and biotechnology companies as our primary customers.

In the injector area, we have licensed our reusable needle-free injection device for use with hGH to Teva, Ferring and JCR. In August 2009, we announced that Teva launched its Tjet® injector system, which uses our needle-free device to administer Teva's Tev-Tropin® brand hGH. We have also licensed both disposable auto and pen injection devices to Teva for use in certain fields and territories. In 2009, we received a payment of $4,076,375 from Teva for tooling and for an advance for the design, development and purchase of additional tooling and automation equipment, all of which is related to a fixed, single-dose, disposable injector product containing epinephrine using our Vibex auto injector platform. In addition, we continue to support existing customers of our reusable needle-free devices for the home or alternate site administration of insulin in the U.S. market through distributors.

In the gel-based area, we recently completed a pivotal Phase 3 trial for our lead product candidate, Anturol®, an oxybutynin ATD gel for the treatment of OAB, for which we expect to file an NDA in 2010. Spending on this program in the first half of 2010 was approximately $2,600,000, and we expect spending in 2010 to be approximately $5,000,000. We also have a partnership with BioSante that includes LibiGel® (transdermal testosterone gel) in Phase 3 clinical development for the treatment of FSD, and Elestrin® (estradiol gel) currently marketed in the U.S for the treatment of moderate-to-severe vasomotor symptoms associated with menopause.

We have operating facilities in the U.S. and Switzerland. Our U.S. operation manufactures and markets our reusable needle-free injection devices and related disposables and develops our disposable pressure-assisted auto injector and pen injector systems. These operations, including all development and some U.S. administrative activities, are located in Minneapolis, Minnesota. Our Pharma division is located both in the U.S. and in Muttenz, Switzerland, where pharmaceutical products are developed utilizing our transdermal systems. Our corporate offices are located in Ewing, New Jersey.

We incurred a net loss of $3,161,197 for the six-month period ended June 30, 2010 and we expect to report a net loss for the year ending December 31, 2010. We have not historically generated sufficient revenue to provide the cash needed to support our operations and have continued to operate primarily by raising capital and incurring debt. In order to better position ourselves to take advantage of potential growth opportunities and to fund future operations, during 2009, we raised additional capital and took steps to reduce our monthly cash obligations. We believe that the combination of our current cash and cash equivalents balance, our recent reductions in our monthly cash outflows, our projected product sales, product development revenue, license revenues, milestone payments and royalties will provide us with sufficient funds to support operations for at least the next 12 months.

Results of Operations

Three and Six Months Ended June 30, 2010 and 2009

Revenues

Total revenues for the three and six months ended June 30, 2010 were $3,050,987 and $6,415,073, compared to revenues for the same prior-year periods of $1,709,566 and $4,074,636. Product revenue was $1,151,978 and $2,478,030 in the three and six months ended June 30, 2010, respectively, compared to $1,168,620 and $1,992,371 in the three and six months ended June 30, 2009, respectively. The slight decrease in the quarter was due to a decrease in sales to Teva which was offset by an increase in sales to Ferring. The Teva sales decrease was due to a higher level of sales in the second quarter of 2009 than in 2010 due to initial sales of needle-free injection devices and disposable components to Teva in anticipation of Teva's launch of our Tjet needle-free device with their hGH Tev-Tropin®, which occurred in August of 2009. The increase in product revenue for the six-month period was due primarily to an increase in sales to Ferring. Development revenue increased in the three and six-month periods to $497,195 and $1,302,442, respectively, in 2010 compared to $321,896 and $1,068,733 in the same periods of the prior year. The increases were primarily due to development work related to our auto injector technology. Licensing revenue also increased in the three and six-month periods to $1,043,845 and $1,879,918, respectively, in 2010 from $107,879

and $805,586, respectively, in 2009. The increases were primarily due to recognition of revenue deferred in 2009 under an Exclusive License Agreement with Ferring, along with milestone payments received from Teva in the second quarter of 2010 and BioSante in the first quarter of 2010. Royalty revenue increased in the three and six-month periods to $357,969 and $754,683, respectively, in 2010 from $111,171 and $207,946 in the same prior-year periods, primarily due to royalties received from Teva in connection with sales of their hGH Tev-Tropin®.

Cost of Revenues and Gross Margins

The cost of product sales are related to our reusable needle free injector devices and disposable components. For the three and six-month periods ended June 30, 2010, cost of product sales was $592,365 and $1,248,825, respectively, compared to $523,931 and $968,047 for the same periods of the prior year. Product gross margins were 49% and 55% in three-month periods ended June 30, 2010 and 2009, respectively, and were 50% and 51% for the six-month periods ended June 30, 2010 and 2009, respectively. The gross margin decrease in the quarter was due mainly to a difference in the mix of products sold.

The cost of development revenue consists primarily of direct external costs, some of which may have been previously incurred and deferred, along with labor costs and an allocation of certain overhead expenses based on actual costs and time spent related to revenue generating development arrangements. Cost of development revenue was $403,596 and $1,062,115 for the three and six-month periods ended June 30, 2010, respectively, compared to $175,235 and $820,289 for the same prior-year periods. The increases in each period were due mainly to increases in development costs recognized related to a License, Development and Supply Agreement with Teva for a product containing epinephrine utilizing our auto injector technology.

Research and Development

The majority of research and development expenses consist of external costs for studies and analysis activities, design work and prototype development. Our most significant projects currently include the following:

- Anturol® oxybutynin gel for treatment of OAB;
- Vibex autoinjector for delivery of epinephrine for emergency treatment of allergic reactions; and
- Vibex MTX autoinjector for delivery of methotrexate for treatment of rheumatoid arthritis.

Although we are engaged in research and development activities involving each of our drug delivery platforms, over 75% of our total research and development expenses in each period were generated in connection with projects related to transdermal gel products, primarily Anturol®. Research and development expenses were $2,242,788 and $4,328,613 in the three and six-month periods ended June 30, 2010, respectively, compared to $1,745,309 and $3,952,068 in the same periods of the prior year. The increase in the first half of 2010 compared to the same period of 2009 was due primarily to our Vibex MTX development program. Since the Vibex epinephrine program is associated with a License, Development and Supply Agreement with Teva, the costs have been deferred and are recognized as cost of revenue when the related revenue is recognized. Expenses incurred related to research and development activities in Switzerland decreased in the first half of 2010 compared to 2009 as a result of the Asset Purchase Agreement with Ferring at the end of 2009.

Sales, Marketing and Business Development

Sales, marketing and business development expenses totaled $241,278 and $571,799 for the three and six-month periods ended June 30, 2010, respectively, compared to $216,863 and $552,380 in the same prior-year periods. Decreases in consulting fees in 2010 were offset by increases in payroll and travel expenses due to the addition of a senior level business development employee in January of this year.

General and Administrative

General and administrative expenses totaled $1,121,957 and $2,339,589 in the three and six-month periods ended June 30, 2010, respectively, compared to $1,140,951 and $2,452,965 in the same periods of the prior year. General and administrative expenses associated with the operations in Switzerland decreased significantly as a result of the transaction with Ferring at the end of 2009. These decreases were partially offset by increases in noncash stock compensation expenses and other payroll expenses.

Other Income (Expense)

Other expense was $1,257 and $25,329 in the three and six-month periods ended June 30, 2010, respectively, compared to expense of $191,690 and $388,655 in the same periods of the prior year. The decrease in expense resulted primarily from a decrease in interest expense due to the retirement of our credit facility in the third quarter of 2009.

Liquidity and Capital Resources

We have not historically generated sufficient revenue to provide the cash needed to support our operations, and we have continued to operate primarily by raising capital and incurring debt. In order to better position ourselves to take advantage of potential growth opportunities and to fund future operations, during 2009, we raised additional capital and took steps to reduce our monthly cash obligations.

In July 2009, we raised gross proceeds of $8,500,000 in a registered direct offering through the sale of shares of our common stock and warrants. We sold a total of 10,625,000 units, each unit consisting of (i) one share of common stock and (ii) one warrant to purchase 0.4 of a share of common stock (or a total of 4,250,000 shares), at a purchase price of $0.80 per unit. The warrants became exercisable six months after issuance at $1.00 per share and will expire five years from the date of issuance.

In September 2009, we raised gross proceeds of $3,000,000 through the sale of 2,727,273 units to certain institutional investors, each unit consisting of (i) one share of common stock and (ii) one warrant to purchase 0.4 of a share of common stock (or a total of 1,090,909 shares), at a purchase price of $1.10 per unit. The warrants became exercisable six months after issuance at $1.15 per share and will expire five years from the date of issuance.

The proceeds from the sale of common stock and warrants in September 2009 were used to pay off the remaining balance of our credit facility, reducing our monthly debt service requirements. The credit facility had originated in 2007, when we received gross proceeds of $7,500,000 in two tranches of $5,000,000 and $2,500,000 to help fund working capital needs. The per annum interest rate was 12.7% in the case of the first tranche and 11% in the case of the second tranche. The maturity date (i) with respect to the first tranche was forty-two months from February 2007 and (ii) with respect to the second tranche was thirty-six months from December 2007.

In the fourth quarter of 2009, we reduced our monthly overhead when we entered into an Asset Purchase Agreement with Ferring. Under this agreement, Ferring assumed responsibility for all of our facility and equipment lease obligations in connection with our operations in Switzerland, and the majority of our employees at that location were hired by Ferring effective January 1, 2010. Subsequent to the Ferring agreement we entered into a month-to-month office lease agreement at a new Swiss location in a much smaller space at a significantly reduced monthly rate.

In the first six months of 2010, we received proceeds of $1,692,826 in connection with exercises of options and warrants to purchase shares of our common stock, which resulted in the issuance of 1,531,101 shares of our common stock.

At June 30, 2010, we had cash and cash equivalents of $11,442,740. We believe that the combination of our current cash and cash equivalents balance and projected product sales, product development, license revenues, milestone payments and royalties will provide us with sufficient funds to support operations for at least the next 12 months. We do not currently have any bank credit lines. In the future, if we need additional financing and are unable to obtain such financing when needed, or obtain it on favorable terms, 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

Net cash used in operating activities was $3,821,907 and $4,754,534 for the six-month periods ended June 30, 2010 and 2009, respectively. The reduction in 2010 compared to 2009 was primarily due to a decrease in the loss for the six-month period to $3,161,197 in 2010 compared to a loss of $5,059,768 in 2009. The decrease in the loss was partially offset by an increase in cash used by changes in operating assets and liabilities. In 2010, changes in operating assets and liabilities resulted in a use of cash of $1,300,143, while in 2009, changes in operating assets and liabilities

resulted in a use of cash of $424,518. The 2010 use of cash was driven primarily by a decrease in accounts payable of $702,299 and deferred revenue of $1,689,494 partially offset by a decrease in accounts receivable of $801,466 and a decrease in deferred costs of $324,615. The 2009 use of cash was driven primarily by a decrease in deferred revenue of $1,350,943 partially offset by a decrease in accounts receivable of $450,566 and a decrease in deferred costs of $449,584.

Net Cash Used in Investing Activities

Net cash used in investing activities was $72,590 and $87,001 for the six-month periods ended June 30, 2010 and 2009, respectively. Cash used for purchases of equipment, molds, furniture and fixtures was $40,434 in 2010 compared to $1,081 in 2009 and additions to patent rights was $47,136 in 2010 compared to $85,920 in 2009. In the first six months of 2010, we received proceeds of $14,980 from the sale of fully depreciated equipment that had been used at our Swiss location.

Net Cash Provided by (Used in) Financing Activities

In the first half of 2010, net cash provided by financing activities consisted of proceeds from exercise of stock options and warrants of $1,692,826. In the first half of 2009, net cash used in financing activities of $1,206,917 consisted of principal payments on long-term debt of $1,260,584 and proceeds from exercise of stock options and warrants of $53,667.

Research and Development Programs

Our current research and development activities are primarily related to Anturol® and device development projects.

Anturol®. We are currently evaluating Anturol® for the treatment of OAB. In July 2010, we completed a Phase III pivotal trial designed to evaluate the efficacy of Anturol® when administered topically once daily for 12 weeks in patients predominantly with urge incontinence episodes. The randomized, double-blind, parallel, placebo-controlled, multi-center trial, involved approximately 600 patients (200 per arm) using two dose strengths (selected from a Phase II clinical trial) versus a placebo. In addition, an Open Label Extension study evaluating long term safety is ongoing and scheduled to be complete by the fourth quarter of 2010. We expect to file an NDA with the FDA in 2010. There is no assurance that the FDA will accept our NDA when filed or that the FDA will ultimately approve Anturol®, and without FDA approval we cannot market or sell Anturol® in the U.S.

We have also incurred significant costs related to Anturol® manufacturing development. We have contracted with Patheon, Inc. ("Patheon"), a manufacturing development company, to supply clinical quantities of Anturol® and to develop a commercial manufacturing process for Anturol®. With Patheon, we have completed limited commercial scale up activities associated with Anturol® manufacturing.

As of June 30, 2010, we have incurred total external costs of approximately $15,500,000 in connection with our Anturol® research and development, of which approximately $2,600,000 was incurred in the first half of 2010. We expect total expenses for Anturol® to be approximately $5,000,000 in 2010. The additional costs relate to the Phase III study closeout costs, safety study costs, NDA compilation costs and manufacturing related costs.

We intend to seek a marketing partner to help fund the development of Anturol® and to commercially launch Anturol® if approved by the FDA. To date, we have not entered into an agreement with a marketing partner.

Device Development Projects. We are 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 an undisclosed product and for our pen injector device for two undisclosed products. We are also developing a Vibex MTX autoinjector for delivery of methotrexate for treatment of rheumatoid arthritis. Our pressure-assisted auto injectors are designed to deliver drugs by injection from single-dose prefilled syringes. The auto injectors are in the advanced commercial stage of development. The disposable pen injector device is designed to deliver drugs by injection through needles from multi-dose cartridges. The disposable pen is in the early stage of development where devices are being evaluated in clinical studies. Our development programs consist of 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.

In the second quarter of 2010 we entered into an agreement with Uman Pharma under which both companies will invest jointly to develop and commercialize Vibex MTX . We will lead the clinical development program, FDA regulatory submissions, and retain rights to commercialize the Vibex MTX product outside of Canada. Uman Pharma will perform formulation development and manufacturing activities to support the registration of Vibex MTX and supply methotrexate in prefilled syringes to us for the U.S. market. Uman Pharma received an exclusive license to commercialize the Vibex MTX product in Canada. The companies intend to work together to commercialize the Vibex MTX product in other territories.

As of June 30, 2010, we have incurred total external costs of approximately $5,400,000 in connection with research and development activities associated with our auto and pen injectors, of which approximately $1,000,000 was incurred in the first half of 2010. As of June 30, 2010, approximately $3,900,000 of the total costs of $5,400,000 was initially deferred, of which approximately $2,800,000 has been recognized as cost of sales and $1,100,000 remains deferred. This remaining deferred balance will be recognized as cost of sales over the same period as the related deferred revenue will be recognized.

The development timelines of the auto and pen injectors related to the Teva products are controlled by Teva. We expect development related to the Teva products to continue in 2010, but the timing and extent of near-term future development will be dependent on certain decisions made by Teva. In 2009, we received a payment from Teva in the amount of $4,076,375 in connection with an amendment to a License, Development and Supply Agreement signed in July 2006 related to a fixed, single-dose, disposable injector product containing epinephrine using our Vibex auto injector platform. Although this payment and certain upfront and milestone payments have been received from Teva, there have been no commercial sales from the auto injector or pen injector programs, timelines have been extended and there can be no assurance that there ever will be commercial sales or future milestone payments under these agreements.

Other research and development costs. In addition to the Anturol® project, Teva related device development projects and our Vibex MTX development project, we incur direct costs in connection with other research and development projects related to our technologies and indirect costs that include salaries, administrative and other overhead costs of managing our research and development projects. Total other research and development costs were approximately $1,300,000 for the six months ended June 30, 2010.

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, 2009. We have made no changes to these policies during the six-month period ended June 30, 2010.

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 the licensing agreement entered into in January 2003 with Ferring, which established pricing in Euros for products sold under the supply agreement and for all royalties. In March 2007, we amended the 2003 agreement with Ferring, establishing prices in U.S. dollars rather than Euros for certain products, reducing the exchange rate risk. Most of our sales and licensing fees 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. Because exposure increases as intercompany balances grow, we will continue to evaluate the need to initiate hedging programs to mitigate the impact of foreign exchange rate fluctuations on intercompany balances. The effect of foreign exchange rate fluctuations on our financial results for the six-month period ended June 30, 2010 was not material.

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. 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 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.

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

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.