ANTARES PHARMA, INC. Form 10-Q May 09, 2011

#### UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2011

Commission File Number 1-32302

ANTARES PHARMA, INC.

A Delaware Corporation

IRS Employer Identification No. 41-1350192

250 Phillips Blvd, Suite 290 Ewing, New Jersey 08618

(609) 359-3020

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

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 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.

Large accelerated filer o

Accelerated filer x

Non –accelerated filer o

Smaller reporting company
o

(do not check if a 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 o No x	
The number of shares outstanding of the registrant's Common Stock, \$.01 par value, as of May 5, 2011 was 88,187,014.	
	,

## ANTARES PHARMA, INC.

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## PART I – FINANCIAL INFORMATION

## Item 1. FINANCIAL STATEMENTS

# ANTARES PHARMA, INC. CONSOLIDATED BALANCE SHEETS

	March 31, 2011 (Unaudited)		December 31, 2010
Assets			
Current Assets:			0.01=01=
Cash and cash equivalents	\$ 13,066,373	\$	9,847,813
Accounts receivable	1,606,796		1,245,560
Inventories	335,026		272,463
Deferred costs	655,481		915,689
Prepaid expenses and other current assets	254,738		193,985
Total current assets	15,918,414		12,475,510
Equipment, molds, furniture and fixtures, net	406,748		327,535
Patent rights, net	838,746		803,426
Goodwill	1,095,355		1,095,355
Deferred costs	-		408,250
Other assets	31,309		31,226
Total Assets	\$ 18,290,572	\$	15,141,302
Liabilities and Stockholders' Equity			
Current Liabilities:			
Accounts payable	\$ 1,972,744	\$	1,773,259
Accrued expenses and other liabilities	673,233		1,818,769
Deferred revenue	3,841,278		3,080,062
Total current liabilities	6,487,255		6,672,090
Deferred revenue – long term	1,013,760		1,842,594
Total liabilities	7,501,015		8,514,684
Stockholders' Equity:			
Preferred Stock: \$0.01 par, authorized 3,000,000 shares, none outstanding	-		_
Common Stock: \$0.01 par; authorized 150,000,000 shares;			
87,803,938 and 84,157,865 issued and outstanding at			
March 31, 2011 and December 31, 2010, respectively	878,039		841,579
Additional paid-in capital	148,833,707		143,318,671
Accumulated deficit	(138,354,428)		(136,973,795)
Accumulated other comprehensive loss	(567,761)		(559,837)
•	10,789,557		6,626,618
Total Liabilities and Stockholders' Equity	\$ 18,290,572	\$	15,141,302

See accompanying notes to consolidated financial statements.

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

		For the Three Months Ended March 31,		*
Revenue:		2011		2010
Product sales	\$	1,405,126	\$	1,326,052
Development revenue	Ψ	1,056,460	Ψ	805,247
Licensing revenue		366,237		836,073
Royalties		741,724		396,714
Total revenue		3,569,547		3,364,086
Cost of revenue:				
Cost of product sales		711,797		656,460
Cost of development revenue		741,044		658,519
Total cost of revenue		1,452,841		1,314,979
Gross profit		2,116,706		2,049,107
Operating expenses:				
Research and development		1,749,336		2,085,825
Sales, marketing and business development		288,794		330,521
General and administrative		1,490,106		1,217,632
		3,528,236		3,633,978
Operating loss		(1,411,530)		(1,584,871)
Other income (expense)		30,897		(24,072)
Net loss	\$	(1,380,633)	\$	(1,608,943)
Basic and diluted net loss per common share	\$	(0.02)	\$	(0.02)
Basic and diluted weighted average common shares outstanding		85,719,683		82,265,477

See accompanying notes to consolidated financial statements.

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

	For the Three Months Ended March 31,			arch 31,
		2011		2010
Cash flows from operating activities:				
Net loss	\$	(1,380,633)	\$	(1,608,943)
Adjustments to reconcile net loss to net cash used in				
operating activities:				
Depreciation and amortization		40,530		44,238
Stock-based compensation expense		471,646		332,617
Changes in operating assets and liabilities:				
Accounts receivable		(364,789)		(202,438)
Inventories		(62,563)		17,013
Prepaid expenses and other current assets		(60,686)		21,217
Deferred costs		668,458		114,566
Accounts payable		200,033		140,963
Accrued expenses and other current liabilities		(1,147,120)		(90,666)
Deferred revenue		(72,182)		(1,151,766)
Net cash used in operating activities		(1,707,306)		(2,383,199)
Cash flows from investing activities:				
Purchases of equipment, molds, furniture and fixtures		(97,910)		(11,277)
Additions to patent rights		(46,554)		(22,743)
Net cash used in investing activities		(144,464)		(34,020)
Cash flows from financing activities:				
Proceeds from exercise of stock options and warrants		5,079,851		412,817
Net cash provided by financing activities		5,079,851		412,817
Effect of exchange rate changes on cash and cash				
equivalents		(9,521)		(8,722)
Net increase (decrease) in cash and cash equivalents		3,218,560		(2,013,124)
Cash and cash equivalents:				
Beginning of period		9,847,813		13,559,088
End of period	\$	13,066,373	\$	11,545,964

See accompanying notes to consolidated financial statements

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

#### 1. Descripton 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<sup>TM</sup> disposable pressure-assisted auto injectors, Vision<sup>TM</sup> 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"), with Teva and Ferring being the Company's two primary customers. The Company's needle-free injection device is used by Teva with the Tjet® injector system to administer their Tev-Tropin® brand hGH marketed in the U.S. and the Company's needle-free injection device is used by Ferring with their 4mg and 10mg hGH formulations marketed as Zomajet® 2 Vision and Zomajet® Vision X, respectively, in Europe and Asia. The Company has also licensed both disposable auto and pen injection devices to Teva for use in certain fields and territories and is engaged in product development activities for Teva utilizing these devices. The Company is currently developing commercial tooling and automation equipment for Teva related to a fixed, single-dose, disposable injector product containing epinephrine using the Company's Vibex<sup>TM</sup> auto injector platform. In addition to development of products with partners, in the first quarter of 2011, the Company initiated a clinical study evaluating its proprietary Vibex<sup>TM</sup> MTX methotrexate injection system being developed for the treatment of rheumatoid arthritis. The Company also continues to support existing customers of its reusable needle-free devices for the administration of insulin in the U.S. market through distributors.

In the gel-based area, the Company received notice from the U.S. Food and Drug Administration ("FDA") in April 2011 of the FDA's acceptance for filing for review of a New Drug Application ("NDA") for Anturol®, an oxybutynin ATD<sup>TM</sup> gel for the treatment of overactive bladder ("OAB"). The NDA submission was supported by a Phase 3 clinical trial conducted by the Company. 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 directs the manufacturing and marketing of the Company's reusable needle-free injection devices and related disposables, and develops its disposable pressure-assisted auto injector and pen injector systems. 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 States of America for interim financial information and with the instructions to Form 10-Q and Article 10 of the Securities and Exchange Commission's Regulation

S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. The accompanying consolidated financial statements and notes should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended December 31, 2010. Operating results for the three months ended March 31, 2011 are not necessarily indicative of the results that may be expected for the year ending December 31, 2011.

## 3. Stockholders' Equity

#### Common Stock

Warrant and stock option exercises in the first three months of 2011 and 2010 resulted in proceeds of \$5,079,851 and \$412,817, respectively, and in the issuance of 3,424,634 and 570,500 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. As of March 31, 2011, the Plan had 1,137,506 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, 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 March 31, 2011, and the changes during the three months then ended is as follows:

			Weighted	
			Average	
		Weighted	Remaining	
		Average	Contractual	Aggregate
	Number of	Exercise	Term	Intrinsic
	Shares	Price (\$)	(Years)	Value (\$)
Outstanding at December 31,				
2010	7,657,876	1.18		
Granted	75,000	1.58		
Exercised	(182,500)	1.19		
Cancelled	(69,550)	3.96		
Outstanding at March 31, 2011	7,480,826	1.16	7.0	5,129,000
Exercisable at March 31, 2011	5,698,510	1.15	6.5	4,026,000

During the first three months of 2011 and 2010 the Company granted options to purchase a total of 75,000 and 200,000 shares of its common stock, respectively. The options were granted at exercise prices of \$1.58 and \$1.30 in 2011 and 2010, respectively, 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 \$230,000 and \$274,000 for the first three months of 2011 and 2010, respectively. As of March 31, 2011, there was approximately \$930,000 of total unrecognized compensation cost related to nonvested outstanding stock options that is expected to be recognized over a weighted average period of approximately two years.

The per share weighted average fair value of options granted during the first three months of 2011 and 2010 were estimated as \$0.82 and \$0.70 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.

	March 31,		
	2011	2010	
Risk-free interest rate	2.2%	2.5%	
Annualized volatility	59.0 <sub>%</sub>	61.0%	
Weighted average expected life, in years	5.0	5.0	
Expected dividend yield	0.0%	0.0%	

In the first quarter of 2011, 3,242,134 warrants with an exercise price of \$1.50 were exercised resulting in proceeds to the Company of \$4,863,201, and 3,502,016 warrants with an exercise price of \$1.50 expired unexercised. Warrants to purchase a total of 10,940,909 shares of common stock were outstanding at March 31, 2011. The weighted average exercise price of the warrants was \$1.60.

The weighted average exercise price of the stock options and warrants outstanding at March 31, 2011 and 2010 was \$1.42 and \$1.44, respectively.

#### Stock Awards

The employment agreements or performance stock bonus 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 shares of the Company's common stock upon the occurrence of various triggering events. As of March 31, 2011, potential future awards under these agreements totaled approximately 425,000 shares of common stock. There were 72,727 and 22,727 shares awarded under these agreements in the first three months of 2011 and 2010, respectively.

At times, the Company grants shares of its common stock to members of management and other employees in lieu of cash bonus awards or in recognition of special achievements. A total of 136,267 and 170,768 shares of common stock were granted as stock awards in the first quarters of 2011 and 2010, respectively. As of March 31, 2011, a total of 181,604 shares granted in prior periods were unvested. 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 \$241,000 and \$52,000 in the first quarters of 2011 and 2010, respectively. The weighted average fair value of the shares granted in 2011 and 2010 was \$1.58 and \$1.30 per share, respectively.

#### 4. Net Loss Per Share

Basic loss per common share is computed by dividing net loss applicable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted loss per common share reflects the potential dilution from the exercise or conversion of securities into common stock. Potentially dilutive stock options

and warrants excluded from dilutive loss per share because their effect was anti-dilutive totaled 18,421,735 and 26,228,393 at March 31, 2011 and 2010, respectively. The table below discloses the basic and diluted loss per common share.

	Three Months Ended March 31,			
		2011		2010
Net loss	\$	(1,380,633)	\$	(1,608,943)
Basic and diluted weighted average common shares				
outstanding		85,719,683		82,265,477
Basic and diluted net loss per common share	\$	(0.02)	\$	(0.02)

## 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 total assets located in two countries as follows:

	March 31,	December 31,
	2011	2010
United States of		
America	\$ 17,720,962	\$ 14,353,760
Switzerland	569,610	787,542
	\$ 18,290,572	\$ 15,141,302

Revenues by customer location are summarized as follows:

	For the Three Months Ended				
	March 31,				
		2011		2010	
United States of					
America	\$	2,239,383	\$	1,700,175	
Europe		1,233,761		1,546,934	
Other		96,403		116,977	
	\$	3,569,547	\$	3,364,086	

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

	For the Three Months Ended				
	March 31,				
	2011	2010			
Teva	\$ 2,132,841	\$ 1,328,038			
Ferring	1,233,762	1,526,937			

#### 6. Comprehensive Loss

	Three Months Ended				
		March 31,			
		2011		2010	
Net loss	\$	(1,380,633)	\$	(1,608,943)	
Change in					
cumulative					
translation					
adjustment		(7,924)		18,043	
Comprehensive					
loss	\$	(1,388,557)	\$	(1,590,900)	

## 7. Revenue Recognition

In January of 2011, the Company amended the license, development and supply agreement with Teva originally entered into in December of 2007 under which the Company will develop and supply a disposable pen injector for use with two undisclosed patient-administered pharmaceutical products. Under the original agreement, an upfront payment, development milestones, and royalties on Teva's product sales, as well as a purchase price for each device sold were to be received by the Company under certain circumstances. Based on an analysis under accounting literature applicable at the time of the agreement, the entire arrangement was considered a single unit of accounting. Therefore, payments received and development costs incurred were deferred and were to be recognized from the start of manufacturing

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through the end of the initial contract period. Changes to the original agreement as a result of the amendment included the following: (i) Teva will pay for future device development activities, (ii) Teva will pay for and own all commercial tooling developed and produced under the agreement, and (iii) certain potential milestone payments were eliminated. The Company has determined that the changes to the agreement as a result of the amendment are a material modification to the agreement. Because the agreement was materially modified, the accounting was re-evaluated under the applicable current revenue recognition accounting standards. The re-evaluation resulted in the agreement being separated into multiple units of accounting and resulted in changes to both the method of revenue recognition and the period over which revenue will be recognized. The provisions of the current standards are to be applied as if they were applicable from inception of the agreement. Under the new accounting, the original license fee received will be recognized as revenue over the development period, the development milestone payments previously received were recognized as revenue immediately and revenue during the manufacturing period will be recognized as devices are sold and royalties are earned. For the three months ended March 31, 2011, the accounting change due to the material modification resulted in recognition of development and licensing revenue previously deferred of \$408,250.

#### 8. New Accounting Pronouncements

In January 2010, the Financial Accounting Standards Board issued Accounting Standards Update 2010-06 (ASU 2010-06), Fair Value Measurements and Disclosures (Topic 820), "Improving Disclosures about Fair Value Measurements." ASU 2010-06 requires new disclosures about significant transfers in and out of Level 1 and Level 2 fair value measurements and the reasons for such transfers and in the reconciliation for Level 3 fair value measurements to disclose separately information about purchases, sales, issuances and settlements. ASU 2010-06 is effective for interim and annual reporting periods beginning after December 15, 2009, except for disclosures about purchases, sales, issuances and settlements in the reconciliation for Level 3 fair value measurements. Those disclosures are effective for fiscal years beginning after December 15, 2010. The adoption of ASU 2010-06 did not have an impact on the Company's consolidated financial statements.

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## ItemMANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF 2. OPERATIONS

#### Forward-Looking Statements

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

- the impact of new accounting pronouncements;
- our expectations regarding the 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 the year ending December 31, 2011; 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 forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements involve known and unknown risks, uncertainties and achievements, and other factors that may cause our or our industry's actual results, levels of activity, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements. While we believe that we have a reasonable basis for each forward-looking statement contained in this report, we caution you that these statements are based on a combination of facts and factors currently known by us and projections of the future about which we cannot be certain. Many factors may affect our ability to achieve our objectives, including:

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

- our inability to attract and retain key personnel;
- adverse economic and political conditions; and

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• 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, 2010 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<sup>TM</sup> disposable pressure-assisted auto injectors, Vision<sup>TM</sup> 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, with Teva and Ferring being our two primary customers. Teva uses our needle-free injection device with the Tjet® injector system to administer Teva's Tev-Tropin® brand hGH marketed in the U.S. and Ferring uses our needle-free injection device with their 4mg and 10mg hGH formulations marketed as Zomajet® 2 Vision and Zomajet® Vision X, respectively, in Europe and Asia. We have also licensed both disposable auto and pen injection devices to Teva for use in certain fields and territories and we are engaged in product development activities for Teva utilizing these devices. We are currently developing commercial tooling and automation equipment for Teva related to a fixed, single-dose, disposable injector product containing epinephrine using our Vibex<sup>TM</sup> auto injector platform. In addition to development of products with partners, in the first quarter of 2011, we initiated a clinical study evaluating our proprietary Vibex<sup>TM</sup> MTX methotrexate injection system being developed for the treatment of rheumatoid arthritis. We also continue to support existing customers of our reusable needle-free devices for the administration of insulin in the U.S. market through distributors.

In the gel-based area, we received notice from the FDA in April 2011 of its acceptance for filing for review of our NDA for Anturol®, an oxybutynin ATD<sup>TM</sup> gel for the treatment of overactive bladder (OAB). The NDA submission was supported by a Phase 3 clinical trial. 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 directs the manufacturing and marketing of our reusable needle-free injection devices and related disposables, and develops our disposable pressure-assisted auto injector and pen injector systems. 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.

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We incurred a net loss of \$1,380,633 for the three-month period ended March 31, 2011 and have accumulated aggregate net losses from the inception of business through March 31, 2011 of \$138,354,428. At March 31, 2011 we had a cash balance of \$13,066,373. We believe that the combination of our current cash and cash equivalents balance, 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 Months Ended March 31, 2011 and 2010

#### Revenues

Total revenue for the three months ended March 31, 2011 was \$3,569,547 compared to \$3,364,086 in the same period of the prior year. Product sales were \$1,405,126 and \$1,326,052 in the first quarters of 2011 and 2010, respectively. Product sales include sales of reusable needle-free injector devices and disposable components, and repairs. Our product sales are generated primarily from sales to Ferring and Teva. Ferring uses our needle-free injector with their 4mg and 10mg hGH formulations marketed as Zomajet® 2 Vision and Zomajet® Vision X, respectively, in Europe and Asia. Teva uses our needle-free injector with the Tjet® injector system to administer their Tev-Tropin® brand hGH marketed in the U.S. The increase in product sales was primarily due to an increase in sales to Ferring.

Development revenue was \$1,056,460 in the first quarter of 2011 compared to \$805,247 in the first quarter of 2010. The revenue in the first quarter of 2011 was primarily due to auto injector and pen injector development work for Teva. In addition, as discussed in Note 7 to the consolidated financial statements, in the first quarter of 2011 we recognized \$304,600 of previously deferred development revenue in connection with an amendment to a license, development and supply agreement with Teva originally entered into in December of 2007 under which we will develop and supply a disposable pen injector for use with two undisclosed patient-administered pharmaceutical products. The revenue in the first quarter of 2010 was primarily due to auto injector development work for Teva.

Licensing revenue was \$366,237 in the first quarter of 2011 compared to \$836,073 in the first quarter of 2010. The licensing revenue in the first quarter of 2011 was primarily due to \$274,444 of revenue previously deferred that was recognized as a result of the amended license, development and supply agreement with Teva for a disposable pen injector, as discussed in Note 7 to the consolidated financial statements. The 2010 licensing revenue was primarily due to recognition of revenue deferred in 2009 under an exclusive license agreement with Ferring, in addition to milestone payments received in connection with an existing license agreement with BioSante.

Royalty revenue was \$741,724 in the first quarter of 2011 compared to \$396,714 in the first quarter of 2010. The increase was 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 primarily related to our reusable injection devices and disposable components. For the three-month period ended March 31, 2011, cost of product sales was \$711,797 compared to \$656,460 for the same period of the prior year. Gross margins were 49% and 50% in three months ended March 31, 2011 and 2010, respectively.

The cost of development revenue consists primarily of direct external costs, some of which may have been previously incurred and deferred. Cost of development revenue was \$741,044 and \$658,519 for the first quarters of 2011 and 2010, respectively. In the first quarter of 2011, \$408,250 was recognized as a result of the amended license,

development and supply agreement with Teva for a disposable pen injector, as discussed in Note 7 to the consolidated financial statements. The remaining development costs in the first quarter of 2011 were due to auto injector and pen injector development work for Teva. The development costs in the first quarter of 2010 were primarily due to auto injector development work for Teva.

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#### Research and Development

The majority of research and development expenses consist of external costs for studies and analysis activities, design work and prototype development. Research and development expenses were \$1,749,336 and \$2,085,825 in the three months ended March 31, 2011 and 2010, respectively. The decrease in the first quarter of 2011 compared to the prior year was due primarily to a decrease in expenses following completion of the Phase III study of Anturol® and filing of our NDA in the fourth quarter of 2010. Expenses related to our transdermal gel products, primarily Anturol®, decreased to less than 30% of our total research and development expenses in the first quarter of 2011 from over 75% in the first quarter of 2010. Partially offsetting this decrease was an increase in expenses related to the initiation of a clinical study evaluating our proprietary Vibex<sup>TM</sup> MTX autoinjector for delivery of methotrexate for the treatment of rheumatoid arthritis, along with an increase in personnel costs due to employee additions.

#### Sales, Marketing and Business Development

Sales, marketing and business development expenses totaled \$288,794 and \$330,521 for the three months ended March 31, 2011 and 2010, respectively. The decrease in 2011 compared to 2010 was primarily related to decreases in professional and legal fees.

#### General and Administrative

General and administrative expenses totaled \$1,490,106 and \$1,217,632 in the three months ended March 31, 2011 and 2010, respectively. The increase was primarily due to increases in patent related expenses, professional fees and noncash compensation expenses.

#### Other Income (Expense)

In the first quarter of 2011 we reported net other income of \$30,897 and in the first quarter of 2010 we reported net other expense of \$24,072. The change was primarily due to recognition of foreign exchange gains in 2011 compared to foreign exchange losses in 2010.

#### Liquidity and Capital Resources

At March 31, 2011, we had cash and cash equivalents of \$13,066,373. 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. Historically, we have not generated sufficient revenue to provide the cash needed to support our operations, and we have continued to operate primarily by raising capital. 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 \$1,707,306 and \$2,383,199 for the three months ended March 31, 2011 and 2010, respectively. The decrease in cash used in operating activities in the first quarter of 2011 compared to 2010 was primarily due to a decrease in the net loss along with an increase in noncash expenses, both from stock based

compensation expense and from costs incurred and deferred in previous periods that were recognized as expense in the current period.

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#### Net Cash Used in Investing Activities

Net cash used in investing activities was \$144,464 in the first three months of 2011 compared to \$34,020 in the first three months of 2010. Cash used for purchases of equipment, molds, furniture and fixtures was \$97,910 in 2011 compared to \$11,277 in 2010 and additions to patent rights was \$46,554 in 2011 compared to \$22,743 in 2010.

#### Net Cash Provided by Financing Activities

Net cash provided by financing activities in the first three months of 2011 and 2010 was \$5,079,851 and \$412,817, respectively, which was due to proceeds from the exercise of stock options and warrants. In the first quarter of 2011, 3,242,134 warrants with an exercise price of \$1.50 were exercised resulting in proceeds of \$4,863,201 and 182,500 options were exercised resulting in proceeds of \$216,650. In the first quarter of 2010, 570,500 options were exercised resulting in proceeds of \$412,817.

## Research and Development Programs

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

Anturol®. We received notice from the FDA in April 2011 of its acceptance for filing for review of our NDA for Anturol®, an oxybutynin ATD<sup>TM</sup> gel 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 was completed in the fourth quarter of 2010. There is no assurance 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 and commercial quantities of Anturol®. With Patheon, we have completed limited commercial scale up activities associated with Anturol® manufacturing.

As of March 31, 2011, we have incurred total external costs of approximately \$18,120,000 in connection with our Anturol® research and development, of which approximately \$340,000 was incurred in 2011.

We intend to seek a marketing partner 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<sup>TM</sup> disposable pressure-assisted auto injectors and our disposable pen injectors. We have signed license agreements with Teva for our Vibex<sup>TM</sup> 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<sup>TM</sup> MTX auto injector 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 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.

In the first quarter of 2011, we initiated a clinical study evaluating our proprietary Vibex<sup>TM</sup> MTX methotrexate injection system being developed for the treatment of rheumatoid arthritis. The clinical study will evaluate several dose strengths of methotrexate delivered with our proprietary Vibex<sup>TM</sup> autoinjector versus conventional needle and syringe administration by a healthcare professional. In 2010, we entered into an agreement with Uman Pharma under which both companies will invest jointly to develop and commercialize Vibex<sup>TM</sup> MTX. We will lead the

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clinical development program and FDA regulatory submissions, and will retain rights to commercialize the Vibex<sup>TM</sup> MTX product outside of Canada. Uman Pharma will perform formulation development and manufacturing activities to support the registration of Vibex<sup>TM</sup> MTX and supply methotrexate in prefilled syringes to us for the U.S. market. Uman Pharma received an exclusive license to commercialize the Vibex<sup>TM</sup> MTX product in Canada. The companies intend to work together to commercialize the Vibex<sup>TM</sup> MTX product in other territories.

As of March 31, 2011, we have incurred total external costs of approximately \$7,000,000 in connection with research and development activities associated with our auto and pen injectors, of which approximately \$600,000 was incurred in 2011. Of this amount, approximately \$470,000 was incurred in connection with our Vibex<sup>TM</sup> MTX development program. We expect spending on this program to be approximately \$2,000,000 in 2011. As of March 31, 2011, approximately \$4,500,000 of the total costs of \$7,000,000 was initially deferred, of which approximately \$3,800,000 has been recognized as cost of sales and \$650,000 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 2011, but the timing and extent of near-term future development will be dependent on certain decisions made by Teva. Although development work payments and certain upfront and milestone payments have been received from Teva, there have been no commercial sales from the auto injector or pen injector programs, timelines have been extended and there can be no assurance that there ever will be commercial sales or future milestone payments under these agreements.

Other research and development costs. In addition to the Anturol® project, the Teva related device development projects and our Vibex<sup>TM</sup> MTX 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 \$900,000 for the quarter ended March 31, 2011.

#### **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, 2010. We have made no changes to these policies during the three-month period ended March 31, 2011.

## ItenQUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK 3.

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

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fluctuations on intercompany balances. The effect of foreign exchange rate fluctuations on our financial results for the three-month period ended March 31, 2011 was not material.

## ItemCONTROLS AND PROCEDURES

4.

#### Disclosure Controls and Procedures

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

#### Internal Control over Financial Reporting

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

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

#### 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, 2010, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K are not the only risks facing us. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

#### **Iten**EXHIBITS

6.

#### (a) Exhibit Index

Exhibit No.	Description
10.1*	Amended and Restated Employment Agreement, dated November 12, 2008, by and between Antares Pharma, Inc. and Dr. Paul K. Wotton.
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.

<sup>\*</sup> Indicates management contract or compensatory plan or arrangement.

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#### **SIGNATURES**

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

## ANTARES PHARMA, INC.

May 9, 2011 /s/ Paul K. Wotton

Dr. Paul K. Wotton

President and Chief Executive Officer

May 9, 2011 /s/ Robert F. Apple

Robert F. Apple

Executive Vice President and Chief Financial

Officer