ANTARES PHARMA, INC. Form 10-Q November 08, 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 September 30, 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 x 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

(do not check if a smaller reporting company)

Smaller reporting company

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

The number of shares outstanding of the registrant's Common Stock, \$.01 par value, as of November 3, 2011 was 103,513,137.

# ANTARES PHARMA, INC.

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## PART I – FINANCIAL INFORMATION

# Item 1. FINANCIAL STATEMENTS

# ANTARES PHARMA, INC. CONSOLIDATED BALANCE SHEETS

		September 30, 2011 (Unaudited)	December 31, 2010
Assets			
Current Assets:		.=	0.04=044
Cash and cash equivalents	\$	17,118,832	\$ 9,847,813
Short-term investments		8,996,150	-
Accounts receivable, net		1,986,786	1,245,560
Inventories, net		351,494	272,463
Deferred costs		1,197,331	915,689
Prepaid expenses and other current assets		255,027	193,985
Total current assets		29,905,620	12,475,510
Long-term investments		6,047,665	-
Equipment, molds, furniture and fixtures, net		494,075	327,535
Patent rights, net		921,563	803,426
Goodwill		1,095,355	1,095,355
Deferred costs		-	408,250
Other assets		31,424	31,226
Total Assets	\$	38,495,702	\$ 15,141,302
Liabilities and Stockholders' Equity			
Current Liabilities:			
Accounts payable	\$	1,829,387	\$ 1,773,259
Accrued expenses and other liabilities	·	1,652,957	1,818,769
Deferred revenue		3,278,789	3,080,062
Total current liabilities		6,761,133	6,672,090
		-, ,	-,,
Deferred revenue – long term		839,795	1,842,594
Total liabilities		7,600,928	8,514,684
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Stockholders' Equity:			
Preferred Stock: \$0.01 par, authorized 3,000,000 shares, none			
outstanding		_	_
Common Stock: \$0.01 par; authorized 150,000,000 shares;			
103,509,310 and 84,157,865 issued and outstanding at			
September 30, 2011 and December 31, 2010, respectively		1,035,093	841,579
Additional paid-in capital		171,634,372	143,318,671
Accumulated deficit		(141,207,784)	(136,973,795)
Accumulated other comprehensive loss		(566,907)	(559,837)
Accumulated other completionsive loss		(300,907)	(339,037)

	30,894,774	6,626,618
Total Liabilities and Stockholders' Equity	\$ 38,495,702 \$	15,141,302

See accompanying notes to consolidated financial statements.

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

	For the Three Months Ended September 30,		For the Nine Months End September 30,		,	
	2011		2010	2011		2010
Revenue:						
Product sales \$	, ,	\$	1,654,215	\$ 5,820,691	\$	4,132,245
Development revenue	952,557		401,723	2,725,275		1,704,165
Licensing revenue	123,419		582,817	608,445		2,462,735
Royalties	646,032		483,305	1,877,046		1,237,988
Total revenue	3,919,037		3,122,060	11,031,457		9,537,133
Cost of revenue:						
Cost of product sales	1,028,376		798,532	2,741,783		2,047,357
Cost of development revenue	778,674		280,982	1,911,397		1,343,097
Total cost of revenue	1,807,050		1,079,514	4,653,180		3,390,454
Gross profit	2,111,987		2,042,546	6,378,277		6,146,679
Operating expenses:						
Research and development	1,429,210		2,332,712	5,124,877		6,661,325
Sales, marketing and business	, ,			, ,		
development	390,260		204,750	1,202,127		776,549
General and administrative	1,559,018		1,170,041	4,325,699		3,509,630
	3,378,488		3,707,503	10,652,703		10,947,504
Operating loss	(1,266,501)		(1,664,957)	(4,274,426)		(4,800,825)
Other income (expense)	(32,758)		33,557	40,437		8,228
Net loss \$		\$	(1,631,400)	\$ (4,233,989)	\$	(4,792,597)
Basic and diluted net loss per common share \$	(0.01)	\$	(0.02)	\$ (0.04)	\$	(0.06)
Basic and diluted weighted average common shares						
outstanding	103,311,772		83,615,043	94,793,953		82,937,306

See accompanying notes to consolidated financial statements.

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

For the Nine Months Ended September 30, 2011 2010 Cash flows from operating activities: \$ Net loss (4,233,989)\$ (4,792,597)Adjustments to reconcile net loss to net cash used in operating activities: Depreciation and amortization 121,469 137,492 Gain on sale of equipment, molds, furniture and fixtures (30,000)(14,980)Stock-based compensation expense 1,488,887 889,188 Changes in operating assets and liabilities: Accounts receivable 626,165 (744,700)Inventories (79,031)42,596 Prepaid expenses and other current assets 68,687 (49,666)Deferred costs 126,608 348,335 (292,715)Accounts payable 55,503 Accrued expenses and other current liabilities (168,336)173,559 Deferred revenue (2,511,529)(824,002)Net cash used in operating activities (4,337,257)(5,325,799)Cash flows from investing activities: Purchases of equipment, molds, furniture and fixtures (227,763)(61,621)Additions to patent rights (153,650)(82,196)Proceeds from sales of equipment, molds, furniture and fixtures 30,000 14,980 Purchases of investment securities (15,053,981)Net cash used in investing activities (15,405,394)(128,837)Cash flows from financing activities: 2,035,480 Proceeds from exercise of stock options and warrants 5,972,900 Proceeds from sale of common stock 21,280,718 Taxes paid related to net share settlement of equity awards (233,291)2,035,480 Net cash provided by financing activities 27,020,327 Effect of exchange rate changes on cash and cash equivalents (6,657)87,152 Net increase (decrease) in cash and cash equivalents 7,271,019 (3,332,004)Cash and cash equivalents: Beginning of period 9,847,813 13,559,088 End of period \$ 17,118,832 \$ 10,227,084

See accompanying notes to consolidated financial statements

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

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#### 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<sup>TM</sup> disposable pressure-assisted auto injectors, Vision<sup>TM</sup> reusable needle-free injectors, and disposable multi-use pen injectors.

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 5mg 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 August 2011, the Company announced positive results from 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. In July 2011, the Company entered into a licensing agreement with Watson Pharmaceuticals, Inc. ("Watson") under which Watson will commercialize Anturol®, once approved. 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 two facilities in the U.S. The Parenteral Products division located in Minneapolis, Minnesota directs the manufacturing and marketing of the Company's reusable needle-free injection devices and related disposables, and develops its disposable pressure-assisted auto injector and pen injector systems. The Company's Pharma division is located in Ewing, New Jersey, where pharmaceutical products are developed utilizing both the Company's transdermal systems and drug/device combination products. The Company's corporate offices are also 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

#### **Table of Contents**

ended December 31, 2010. Operating results for the nine months ended September 30, 2011 are not necessarily indicative of the results that may be expected for the year ending December 31, 2011.

#### Investments

All short-term and long-term investments are U.S. Treasury bills or U.S. Treasury notes that are classified as held-to-maturity because the Company has the positive intent and ability to hold the securities to maturity. The securities are carried at their amortized cost. The fair value of all securities is determined by quoted market prices. All long-term investments mature in less than two years. At September 30, 2011 the short-term investments had a fair value of \$8,995,140 and a carrying value of \$8,996,150 and the long-term investments had a fair value of \$6,039,369 and a carrying value of \$6,047,665.

# 3. Stockholders' Equity

#### Common Stock

In May 2011, the Company sold a total of 14,375,000 shares of common stock at a price of \$1.60 per share in a public offering, which resulted in net proceeds of \$21,280,718 after deducting offering expenses of \$1,719,282.

Warrant and stock option exercises in the first nine months of 2011 and 2010 resulted in proceeds of \$5,972,900 and \$2,035,480, respectively, and in the issuance of 4,439,008 and 1,804,884 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 ten to eleven years and they vest in varying periods. In May 2011, the shareholders approved an amendment to the Plan to increase the maximum number of shares authorized for issuance by 2,000,000 to 13,500,000 from 11,500,000. As of September 30, 2011, the Plan had 1,718,358 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 September 30, 2011, and the changes during the nine months then ended is as follows:

			Weighted	
			Average	
		Weighted	Remaining	
	Number	Average	Contractual	Aggregate
	of	Exercise	Term	Intrinsic
	Shares	Price (\$)	(Years)	Value (\$)
Outstanding	a t			
December 31, 2010	7,657,876	1.18		
Granted	971,409	1.75		
Exercised	(713,736)	1.37		
Cancelled	(69,550)	3.96		
Outstanding	a t			
September 30, 2011	7,845,999	1.21	7.0	8,987,230
Exercisable	a t			
September 30, 2011	5,993,359	1.12	6.4	7,456,011

During the first nine months of 2011 and 2010 the Company granted options to purchase a total of 971,409 and 647,487 shares of its common stock, respectively. The options were granted at weighted average exercise prices of \$1.75 and \$1.49 in 2011 and 2010, respectively. 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 \$699,600 and \$648,000 for the first nine months of 2011 and 2010, respectively. As of September 30, 2011, there was approximately \$1,185,000 of total unrecognized compensation cost related to nonvested outstanding stock options that is expected to be recognized over a weighted average period of approximately 1.7 years.

The per share weighted average fair value of options granted during the first nine months of 2011 and 2010 were estimated as \$0.89 and \$0.79 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.

	Septemb	er 30,
	2011	2010
Risk-free interest rate	1.7%	2.1%
Annualized volatility	58.5%	61.0%
Weighted average expected life, in years	5.0	5.0
Expected dividend yield	0.0%	0.0%

In the first nine months of 2011, 3,307,759 warrants with exercise prices ranging from \$1.50 to \$2.00 were exercised resulting in proceeds to the Company of \$4,994,450 and 800,000 warrants with an exercise price of \$0.80 were exercised under a cashless provision resulting in the issuance of 417,513 shares of common stock. A total of 3,502,016 warrants with an exercise price of \$1.50 expired unexercised. Warrants to purchase a total of 10,075,284 shares of common stock were outstanding at September 30, 2011. The weighted average exercise price of the warrants was \$1.66.

The weighted average exercise price of the stock options and warrants outstanding at September 30, 2011 and 2010 was \$1.46 and \$1.44, respectively.

#### Stock Awards

The employment agreements or performance stock bonus agreements with certain 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 September 30, 2011, potential future awards under these agreements totaled approximately 275,000 shares of common stock. There were 145,454 and 45,454 shares awarded under these agreements in the first nine 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 408,267 and 213,268 shares of common stock were granted as stock awards in the first nine months of 2011 and 2010, respectively. As of September 30, 2011, a total of 158,780 shares previously granted 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 \$754,460 and \$213,800 in the first nine months of 2011 and 2010, respectively. The weighted average fair value of the shares granted in 2011 and 2010 was \$1.81 and \$1.34 per share, respectively. A portion of the shares vested in 2011 were net-share settled such that the Company withheld shares with value equivalent to the employees' minimum statutory obligation for the applicable income and other employment taxes, and remitted the cash to the appropriate taxing authorities. The total shares withheld were 121,182, and were based on the value of the shares on their vesting date as determined by the Company's closing stock price. Total payments for the employees' tax obligations to the taxing authorities were \$233,291 and are reflected as a financing activity within the Consolidated Statements of Cash Flows. These net-share settlements had the effect of share repurchases by the Company as they reduced the number of shares that would have otherwise been issued as a result of the vesting and did not represent an expense to the Company.

#### Long Term Incentive Program

On May 17, 2011, the Board of Directors of the Company approved a new long term incentive program for the benefit of its executive officers. Pursuant to the long term incentive program, the Company's executive officers were awarded stock options and performance stock units with a value targeted at the median level of the Company's peer group as disclosed in its 2011 definitive proxy statement. Two thirds of that value for each officer is delivered in the form of stock options and one third of that value is delivered in the form of performance stock units. A total of 317,000 options were granted on May 17, 2011 under this program. The stock options (i) have a ten-year term, (ii) have an exercise price equal to the closing price of the Company's common stock, as reported on AMEX, on the date of grant (\$1.66), (iii) vest in quarterly installments over three years, and (iv) were otherwise granted on the same standard terms and conditions as other stock options granted pursuant to the Plan. The performance stock unit awards made to the executive officers will be vested and convert into actual shares of the Company's common stock based on the Company's attainment of certain performance goals measured over the three-year period beginning January 1, 2011 and ending December 31, 2013 and the executive officer's continued employment with the Company through that period. Each performance criterion has levels of achievement designated as threshold, target and maximum with 50% of the performance stock units vesting if the threshold level is achieved; 100% of the performance stock units vesting if the target level is achieved and 150% of the performance stock units vesting if the maximum level is achieved. A total of 182,000 performance stock units were awarded at the target level. In the event that the actual performance level achieved does not meet threshold performance (i.e., less than 50%) for an applicable performance measure, then no performance stock units will be earned and vested for that performance measure. Threshold level performance may be achieved for one performance measure and not another based on the Company's actual performance during the three year performance period.

#### 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 17,921,283 and

25,225,596 at September 30, 2011 and 2010, respectively. The table below discloses the basic and diluted loss per common share.

	Three Mon	ths	Ended	Nine Mon	ths	Ended
	Septemb	er i	30,	Septemb		30,
	2011		2010	2011		2010
Net loss	\$ (1,299,259)	\$	(1,631,400) \$	(4,233,989)	\$	(4,792,597)
Basic and diluted weighted average common shares						
outstanding	103,311,772		83,615,043	94,793,953		82,937,306
Basic and diluted						
net loss per						
common share	\$ (0.01)	\$	(0.02) \$	(0.04)	\$	(0.06)

# 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.

Revenues by customer location are summarized as follows:

	Three Months Ended September 30,			ths Ended lber 30,		
	2011		2010	2011		2010
United States of						
America	\$ 2,525,192	\$	1,500,552	\$ 6,338,645	\$	4,746,888
Europe	1,292,370		1,557,820	4,323,273		4,513,015
Other	101,475		63,688	369,539		277,230
	\$ 3,919,037	\$	3,122,060	\$ 11.031.457	\$	9,537,133

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

	Three Mor	nths Ended	Nine Mon	ths Ended
	Septem	Septem	ber 30,	
	2011	2010	2011	2010
Teva	\$ 1,945,134	\$1,290,478	\$5,519,202	\$3,953,783
Ferring	1,287,009	1,557,819	4,321,573	4,473,920
Watson	432,353	_	432,353	_

# 6. Comprehensive Loss

	Three Mon	ths Ended	Nine Mon	ths Ended
	Septem	ber 30,	Septem	ber 30,
	2011	2010	2011	2010
Net loss	\$ (1,299,259)	\$ (1,631,400)	\$ (4,233,989)	\$ (4,792,597)
Change in cumulative	(33,375)	(41,977)	(7,070)	43,161

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translation adjustment

Comprehensive loss \$ (1,332,634) \$ (1,673,377) \$ (4,241,059) \$ (4,749,436)

## 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 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 nine months ended September 30, 2011, the accounting change resulting from the material modification resulted in recognition of development and licensing revenue previously deferred of \$304,600 and \$316,666, respectively, and recognition of costs previously deferred of \$408,250.

# 8. License Agreements

On July 11, 2011, the Company announced with Watson Pharmaceuticals, Inc. an exclusive licensing agreement for Watson to commercialize the Company's topical oxybutynin gel product, Anturol®, in the U.S. and Canada. A New Drug Application for Anturol® is currently under review by the Food and Drug Administration ("FDA"). The FDA has assigned a Prescription Drug User Fee Act ("PDUFA") date of December 8, 2011.

Under terms of the agreement, Watson will make payments for certain manufacturing start-up activities and will make milestone payments based on the achievement of regulatory approval and certain sales levels. Upon launch of the product, the Company will receive escalating royalties based on product sales in the U.S. and Canada. A portion of the milestone payments based on the achievement of regulatory approval is subject to reimbursement to Watson if launch quantities are not delivered within a certain defined time period. After delivery of initial launch quantities to Watson by the Company, Watson will assume responsibility for manufacture and supply of the product.

Arrangement consideration will be allocated to the separate units of accounting based on the relative selling prices. Selling prices are determined using vendor specific objective evidence ("VSOE"), when available, third-party evidence ("TPE"), when available, or an estimate of selling price when neither of the first two options is available for a given unit of accounting. Selling prices in this arrangement were determined using estimated selling prices because VSOE and TPE were not available. The primary factors considered in determining selling price estimates in this arrangement were estimated costs, reasonable margin estimates and historical experience.

As is typical with the Company's multi-element arrangements, the Company has determined that the license and development activities, which include the manufacturing start-up activities, do not have value to the customer on a stand-alone basis as proprietary knowledge about the product and technology is required to complete the development activities. As a result, these deliverables do not qualify for treatment as separate units of accounting. Accordingly, the license and development activities will be accounted for as a single unit of accounting and arrangement consideration allocated to these deliverables will be recognized as revenue over the development period, which ends upon delivery of launch quantities. The sales based milestone payments will be recognized as revenue when earned, revenue for launch quantities will be recognized when product is delivered to Watson and royalties will be recognized as revenue when earned. Revenue recognition for a portion of the milestone payments based on the achievement of

regulatory approval will be dependent upon delivery of launch quantities to Watson by the Company. For the three-month and nine-month periods ended September, 30, 2011, the Company has recognized revenue of \$432,000 in connection with manufacturing start-up activities.

## 9. New Accounting Pronouncements

In January 2010, the Financial Accounting Standards Board ("FASB") 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.

In April 2010, the FASB issued authoritative 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 recent guidance discusses the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. The guidance is effective for fiscal years and interim periods within those years beginning on or after June 15, 2010, with early adoption permitted. This guidance was effective for us on January 1, 2011. Adoption of this guidance has not had a material impact on the Company's consolidated financial statements as the Company has not received any milestone payments after the effective date.

# Item ANAGEMENT'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:

- our expectations regarding the product development and manufacturing 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;
- 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; and
  - the impact of new accounting pronouncements.

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;
  - 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
- 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.

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 their 5mg 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 August 2011, we announced positive results from 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. In July 2011, we entered into a licensing agreement with Watson Pharmaceuticals, Inc. under which Watson will commercialize Anturol®, once approved. 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 two facilities in the U.S. Our Parenteral Products division located in Minneapolis, Minnesota directs the manufacturing and marketing of our reusable needle-free injection devices and related disposables, and develops our disposable pressure-assisted auto injector and pen injector systems. Our Pharma division is located in Ewing, New Jersey, where pharmaceutical products are developed utilizing both our transdermal systems and drug/device combination products. Our corporate offices are also located in Ewing, New Jersey.

We incurred a net loss of \$4,233,989 for the nine-month period ended September 30, 2011 and have accumulated aggregate net losses from the inception of business through September 30, 2011 of \$141,207,784. At September 30,

2011 we had total cash and investments of \$32,162,647. We believe that the combination of our current cash and investments balances, our projected product sales, product development revenue, license revenue, milestone payments and royalties will provide us with sufficient funds to support operations for at least the next 24 months.

#### **Results of Operations**

Three and Nine Months Ended September 30, 2011 and 2010

#### Revenues

Total revenues for the three and nine-month periods ended September 30, 2011 were \$3,919,037 and \$11,031,457, respectively, compared to revenues for the same prior-year periods of \$3,122,060 and \$9,537,133, respectively. Product revenue was \$2,197,029 and \$5,820,691 in the three and nine-month periods ended September 30, 2011, respectively, compared to \$1,654,215 and \$4,132,245, in the three and nine-month periods ended September 30, 2010, respectively. Product sales include sales of reusable needle-free injector devices and disposable components. 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 5mg Tev-Tropin® brand hGH marketed in the U.S. Product sales to both Ferring and Teva increased in the three and nine-month periods ended September 30, 2011 compared to the same periods of 2010.

Development revenue was \$952,557 and \$2,725,275 in the three and nine-month periods ended September 30, 2011, respectively, compared to \$401,723 and \$1,704,165 in the same periods of the prior year. The revenue in the three-month and nine-month periods ended September 30, 2011 included approximately \$432,000 earned under the Watson license agreement and the remaining revenue in each period 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 nine months of 2011, we recognized \$304,600 of previously deferred development revenue in connection with an amendment, in the first quarter of 2011, 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 nine months of 2010 was primarily due to auto injector development work for Teva.

Licensing revenue was \$123,419 and \$608,445 in the three and nine-month periods ended September 30, 2011, respectively, compared to \$582,817 and \$2,462,735 in the same periods of 2010. The licensing revenue in the three and nine-month periods ended September 30, 2011 included recognition of revenue previously deferred in connection with license agreements with Teva, Ferring and BioSante, but in the nine-month period licensing revenue was primarily due to \$316,666 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 from Teva in the second quarter of 2010 and BioSante in the first quarter of 2010.

Royalty revenue was \$646,032 and \$1,877,046 in the three and nine-month periods ended September 30, 2011, respectively, compared to \$483,305 and \$1,237,988 in the same prior-year periods. The increases were primarily due to royalties received from Teva in connection with an increase in sales of their hGH Tev-Tropin® and Ferring in connection with an increase in device sales.

# Cost of Revenues and Gross Margins

The cost of product sales is related to our reusable needle-free injection devices and disposable components. For the three and nine-month periods ended September 30, 2011, cost of product sales was \$1,028,376 and \$2,741,783, respectively, compared to \$798,532 and \$2,047,357 for the same periods of the prior year. Product gross margins were 53% and 52% in three-month periods ended September 30, 2011 and 2010, respectively, and were 53% and 50% for the nine-month periods ended September 30, 2011 and 2010, respectively. The product gross margin increase to 53% in the first nine months of 2011 compared to 50% in the first nine months of 2010 was primarily due

to selling price increases and due to a significant increase in sales volume without a significant increase in fixed overhead expenses.

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 \$778,674 and \$1,911,397 for the three and nine-month periods ended September 30, 2011, respectively, compared to \$280,982 and \$1,343,097 for the same prior-year periods. In the three-month period ended September 30, 2011, approximately \$432,000 of costs were related to certain development activities under the Watson license agreement. In the first nine months of 2011, \$408,250 of costs previously deferred were 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 nine months of 2011 were due to auto injector and pen injector development work for Teva. The development costs in the first nine months of 2010 were primarily due to auto injector development work for Teva.

#### 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 \$1,429,210 and \$5,124,877 in the three and nine-month periods ended September 30, 2011, respectively, compared to \$2,332,712 and \$6,661,325 in the same periods of the prior year. The decrease in the three and nine-month periods ended September 30, 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 10% and 25% of our total research and development expenses in the three and nine-month periods ended September 30, 2011, respectively, from approximately 75% in the same periods of 2010. Partially offsetting this decrease was an increase in expenses related to development of our proprietary VIBEX<sup>TM</sup> MTX auto injector 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 \$390,260 and \$1,202,127 for the three and nine-month periods ended September 30, 2011, respectively, compared to \$204,750 and \$776,549 in the same prior-year periods. The increases in each period were primarily due to increases in legal costs in connection with potential partner agreements and professional fees related to market research, along with increases in payroll related expenses, much of which was noncash stock compensation expense.

#### General and Administrative

General and administrative expenses totaled \$1,559,018 and \$4,325,699 in the three and nine-month periods ended September 30, 2011, respectively, compared to \$1,170,041 and \$3,509,630 in the same periods of the prior year. The increases in each period were primarily due to increases in payroll related expenses, primarily noncash stock compensation expense, patent related expenses and professional fees.

#### Other Income (Expense)

Other income (expense) was (\$32,758) and \$40,437 in the three and nine-month periods ended September 30, 2011, respectively, compared to other income of \$33,557 and \$8,228 in the same periods of the prior year. The changes in the periods were primarily due to changes in foreign exchange gains and losses and increases in interest income in 2011 compared to 2010.

## Liquidity and Capital Resources

At September 30, 2011, our cash and investments totaled \$32,162,647, which consisted of cash and cash equivalents of \$17,118,832, short-term investments of \$8,996,150 and long-term investments of \$6,047,665. All investments are U.S. Treasury bills or U.S. Treasury notes which we intend to hold to maturity.

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We believe that the combination of our current cash and investments balances, projected product sales, product development revenue, license revenue, milestone payments and royalties will provide us with sufficient funds to support operations for at least the next 24 months.

Cash Flows

Net Cash Used in Operating Activities

Net cash used in operating activities was \$4,337,257 and \$5,325,799 for the nine months ended September 30, 2011 and 2010, respectively. The decrease in cash used in operating activities in the first nine months of 2011 compared to 2010 was primarily due to a decrease in net loss along with an increase in noncash stock based compensation expenses.

Net Cash Used in Investing Activities

Net cash used in investing activities was \$15,405,394 in the first nine months of 2011 compared to \$128,837 in the first nine months of 2010. In 2011, \$15,053,981 of cash was used to purchase investment securities, while no securities were purchased in 2010. Cash used for purchases of equipment, molds, furniture and fixtures was \$227,763 in 2011 compared to \$61,621 in 2010 and additions to patent rights was \$153,650 in 2011 compared to \$82,196 in 2010.

Net Cash Provided by Financing Activities

Net cash provided by financing activities in the first nine months of 2011 and 2010 was \$27,020,327 and \$2,035,480, respectively. The increase in 2011 was primarily due to net proceeds of \$21,280,718 received in May 2011 from the sale of 14,375,000 shares of our common stock at \$1.60 per share in a public offering. In addition, we received proceeds of \$5,972,900 in the first nine months of 2011 from the exercise of 3,307,759 warrants resulting in proceeds of \$4,994,450 and 713,736 options resulting in proceeds of \$978,450. In the first nine months of 2011, total payments for employees' income and employment tax obligations related to net share settlement of equity awards was \$233,291. In the first nine months of 2010, warrant and option exercises resulted in proceeds of \$2,035,480.

#### Research and Development Programs

Our current research and development activities are primarily related to Anturol®, VIBEX<sup>TM</sup> MTX 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, Anturol® cannot be marketed or sold 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 September 30, 2011, we have incurred total external costs of approximately \$18,800,000 in connection with our Anturol® research and development, of which approximately \$1,000,000 was incurred in 2011. We recognized revenue of approximately \$432,000 for certain development activities in connection with the July 2011 license agreement under which Watson will commercialize Anturol®, once approved.

VIBEX<sup>TM</sup> MTX. We are developing VIBEX<sup>TM</sup> MTX auto injector for delivery of methotrexate for treatment of rheumatoid arthritis. In August 2011, we announced positive results from a clinical study initiated in the first quarter of 2011 evaluating our proprietary VIBEX<sup>TM</sup> MTX methotrexate injection system. The clinical study evaluated several dose strengths of methotrexate delivered with our VIBEX<sup>TM</sup> auto injector 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 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 September 30, 2011, we have incurred external costs of approximately \$2,200,000 in connection with our VIBEX<sup>TM</sup> MTX development program, of which approximately \$1,650,000 was incurred in 2011. We expect spending on this program to be approximately \$2,000,000 in 2011.

Device Development Projects. We are also 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. 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.

As of September 30, 2011, we have incurred total external costs of approximately \$7,700,000 in connection with research and development activities associated with our auto and pen injectors, of which approximately \$1,800,000 was incurred in 2011. As of September 30, 2011, approximately \$5,800,000 of the total costs of \$7,700,000 was initially deferred, of which approximately \$4,600,000 has been recognized as cost of sales and \$1,200,000 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, our VIBEX<sup>TM</sup> MTX project and the Teva related device development projects, we incur direct costs in connection with other research and development projects related to our technologies and indirect costs that include salaries, administrative and other overhead costs of managing our research and development projects. Total other research and development costs were approximately \$2,900,000 for the nine months ended September 30, 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 nine-month period ended September 30, 2011.

# Recently Issued Accounting Pronouncements

In June 2011, the FASB issued ASU 2011-05, Comprehensive Income (Topic 220), "Presentation of Comprehensive Income." Under ASU 2011-05 an entity has the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In both choices, an entity is required to present each component of net income along with total net income, each component of other comprehensive income along with a total for other comprehensive income, and a total amount for comprehensive income. ASU 2011-05 eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. ASU 2011-05 does not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. ASU 2011-05 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2011. Because ASU 2011-05 impacts presentation only, it will have no effect on our consolidated financial statements or on our financial condition.

In May 2011, the FASB issued updated accounting guidance related to fair value measurements and disclosures that result in common fair value measurements and disclosures between Generally Accepted Accounting Principles and International Financial Reporting Standards. This guidance includes amendments that clarify the intent about the application of existing fair value measurements and disclosures, while other amendments change a principle or requirement for fair value measurements or disclosures. This guidance is effective for interim and annual periods beginning after December 15, 2011. The new guidance is to be adopted prospectively and early adoption is not permitted. We do not believe the adoption of this guidance will have a material impact on our consolidated financial statements.

#### Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our primary market risk exposure is foreign exchange rate fluctuations of the Swiss Franc to the U.S. dollar as the financial position and operating results of our subsidiaries in Switzerland are translated into U.S. dollars for consolidation. Our exposure to foreign exchange rate fluctuations also arises from transferring funds to our Swiss subsidiaries in Swiss Francs. In addition, we have exposure to exchange rate fluctuations between the Euro and the U.S. dollar in connection with a licensing agreement with Ferring, under which certain products sold to Ferring and royalties are denominated in Euros. Most of our product sales, including a portion of our product sales to Ferring, and our development and licensing fees and royalties are denominated in U.S. dollars, thereby significantly mitigating the risk of exchange rate fluctuations on trade receivables. We do not currently use derivative financial instruments to hedge against exchange rate risk. The effect of foreign exchange rate fluctuations on our financial results for the nine-month period ended September 30, 2011 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. 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

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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.

#### Item 6. EXHIBITS

#### (a) Exhibit Index

Exhibit No. 31.1	Description  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.

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#### **SIGNATURES**

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

## ANTARES PHARMA, INC.

November 8, 2011 /s/ Paul K. Wotton

Dr. Paul K. Wotton

President and Chief Executive Officer

November 8, 2011 /s/ Robert F. Apple

Robert F. Apple

Executive Vice President and Chief Financial

Officer