

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

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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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, 2010

Commission File Number 1-32302

ANTARES PHARMA, INC.

A Delaware Corporation  
No. 41-1350192

IRS Employer Identification

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 [ ]

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes [ ] No [ ]

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

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Large accelerated filer       Accelerated filer       Non –accelerated filer       Smaller reporting company

(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  No

The number of shares outstanding of the registrant’s Common Stock, \$.01 par value, as of November 09, 2010, was 83,777,551.

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## PART I – FINANCIAL INFORMATION

## Item 1. FINANCIAL STATEMENTS.

ANTARES PHARMA, INC.  
CONSOLIDATED BALANCE SHEETS

	September 30, 2010 (Unaudited)	December 31, 2009
Assets		
Current Assets:		
Cash and cash equivalents	\$ 10,227,084	\$ 13,559,088
Accounts receivable	823,543	1,542,272
Inventories	286,957	329,553
Deferred costs	621,200	963,053
Prepaid expenses and other current assets	84,678	155,255
Total current assets	12,043,462	16,549,221
Equipment, molds, furniture and fixtures, net	312,933	317,310
Patent rights, net	776,208	742,399
Goodwill	1,095,355	1,095,355
Deferred costs	408,250	408,250
Other assets	31,077	30,838
Total Assets	\$ 14,667,285	\$ 19,143,373
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	\$ 1,578,602	\$ 1,882,158
Accrued expenses and other liabilities	1,248,700	1,048,619
Deferred revenue	2,947,856	5,311,516
Total current liabilities	5,775,158	8,242,293
Deferred revenue – long term	1,889,756	2,050,550
Total liabilities	7,664,914	10,292,843
Stockholders' Equity:		
Preferred Stock: \$0.01 par, authorized 3,000,000 shares, none outstanding	-	-
Common Stock: \$0.01 par; authorized 150,000,000 shares; 83,777,551 and 81,799,541 issued and outstanding at September 30, 2010 and December 31, 2009, respectively	837,778	817,995
Additional paid-in capital	142,495,953	139,614,459
Accumulated deficit	(135,675,194)	(130,882,597)
Accumulated other comprehensive loss	(656,166)	(699,327)
	7,002,371	8,850,530
Total Liabilities and Stockholders' Equity	\$ 14,667,285	\$ 19,143,373

See accompanying notes to consolidated financial statements.

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

	For the Three Months Ended		For the Nine Months Ended	
	September 30, 2010	2009	September 30, 2010	2009
<b>Revenue:</b>				
Product sales	\$ 1,654,215	\$ 923,155	\$ 4,132,245	\$ 2,915,526
Development revenue	401,723	293,899	1,704,165	1,362,632
Licensing revenue	582,817	360,776	2,462,735	1,166,362
Royalties	483,305	76,953	1,237,988	284,899
<b>Total revenue</b>	<b>3,122,060</b>	<b>1,654,783</b>	<b>9,537,133</b>	<b>5,729,419</b>
<b>Cost of revenue:</b>				
Cost of product sales	798,532	510,234	2,047,357	1,478,281
Cost of development and licensing revenue	280,982	246,121	1,343,097	1,066,410
<b>Total cost of revenue</b>	<b>1,079,514</b>	<b>756,355</b>	<b>3,390,454</b>	<b>2,544,691</b>
<b>Gross profit</b>	<b>2,042,546</b>	<b>898,428</b>	<b>6,146,679</b>	<b>3,184,728</b>
<b>Operating expenses:</b>				
Research and development	2,332,712	2,004,921	6,661,325	5,956,989
Sales, marketing and business development	204,750	173,797	776,549	726,177
General and administrative	1,170,041	1,262,554	3,509,630	3,715,519
	3,707,503	3,441,272	10,947,504	10,398,685
<b>Operating loss</b>	<b>(1,664,957)</b>	<b>(2,542,844)</b>	<b>(4,800,825)</b>	<b>(7,213,957)</b>
<b>Other income (expense):</b>				
Interest income	12,430	951	21,327	25,973
Interest expense	(942)	(270,157)	(3,420)	(629,947)
Foreign exchange gains (losses)	22,012	(5,532)	(13,491)	(33,703)
Other, net	57	(6,802)	3,812	(32,518)
	33,557	(281,540)	8,228	(670,195)
<b>Net loss</b>	<b>\$ (1,631,400)</b>	<b>\$ (2,824,384)</b>	<b>\$ (4,792,597)</b>	<b>\$ (7,884,152)</b>
<b>Basic and diluted net loss per common share</b>	<b>\$ (0.02)</b>	<b>\$ (0.04)</b>	<b>\$ (0.06)</b>	<b>\$ (0.11)</b>
<b>Basic and diluted weighted average common shares outstanding</b>	<b>83,615,043</b>	<b>75,870,525</b>	<b>82,937,306</b>	<b>70,702,423</b>

See accompanying notes to consolidated financial statements.

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

	For the Nine Months Ended September 30,	
	2010	2009
Cash flows from operating activities:		
Net loss	\$ (4,792,597)	\$ (7,884,152)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	137,492	175,706
Gain on sale of equipment, molds, furniture and fixtures	(14,980)	-
Stock-based compensation expense	889,188	884,379
Amortization of debt discount and issuance costs	-	206,519
Changes in operating assets and liabilities:		
Accounts receivable	626,165	823,715
Inventories	42,596	(144,792)
Prepaid expenses and other current assets	68,687	40,274
Deferred costs	348,335	178,399
Accounts payable	(292,715)	(196,124)
Accrued expenses and other current liabilities	173,559	366,448
Deferred revenue	(2,511,529)	2,534,619
Net cash used in operating activities	(5,325,799)	(3,015,009)
Cash flows from investing activities:		
Purchases of equipment, molds, furniture and fixtures	(61,621)	(1,081)
Additions to patent rights	(82,196)	(117,903)
Proceeds from sales of equipment, molds, furniture and fixtures	14,980	-
Net cash used in investing activities	(128,837)	(118,984)
Cash flows from financing activities:		
Proceeds from exercise of stock options and warrants	2,035,480	95,322
Proceeds from sale of common stock	-	10,527,650
Principal payments on long-term debt	-	(5,014,390)
Net cash provided by financing activities	2,035,480	5,608,582
Effect of exchange rate changes on cash and cash equivalents	87,152	(14,596)
Net increase (decrease) in cash and cash equivalents	(3,332,004)	2,459,993
Cash and cash equivalents:		
Beginning of period	13,559,088	13,096,298
End of period	\$ 10,227,084	\$ 15,556,291





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

1. Description of Business

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

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

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

The Company has operating facilities in the U.S. and Switzerland. The U.S. operation manufactures and markets the Company’s reusable needle-free injection devices and related disposables, and develops its disposable pressure-assisted auto injector and pen injector systems. These operations, including all development and some U.S. administrative activities, are located in Minneapolis, Minnesota. The Company’s Pharma division is located both in the U.S. and in Muttens, 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, 2009. Operating results for the three and nine-month periods ended September 30, 2010 are not necessarily indicative of the results that may be expected for the year ending December 31, 2010.

### 3. Stockholders' Equity

#### Common Stock

Warrant and stock option exercises in the first nine months of 2010 and 2009 resulted in proceeds of \$2,035,480 and \$95,322, respectively, and in the issuance of 1,804,884 and 137,916 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 the options vest in varying periods. In May 2010, the shareholders approved an amendment to the Plan to increase the maximum number of shares authorized for issuance by 1,500,000 from 10,000,000 to 11,500,000. As of September 30, 2010, the Plan had 1,886,522 shares available for grant. The number of shares available for grant does not take into consideration potential stock awards that could result in the issuance of shares of common stock if certain performance conditions are met, as discussed under "Stock Awards" below. Stock option exercises are satisfied through the issuance of new shares.

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

	Number of Shares	Weighted Average Exercise Price (\$)	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (\$)
Outstanding at December 31, 2009	8,339,684	1.13		
Granted	647,487	1.49		
Exercised	(1,334,434)	1.00		
Cancelled	(252,100 )	2.07		
Outstanding at September 30, 2010	7,400,637	1.15	7.0	3,080,000
Exercisable at September 30, 2010	5,535,719	1.22	6.5	2,140,000



During the first nine months of 2010, the Company granted options to purchase a total of 647,487 shares of its common stock at exercise prices ranging from \$1.30 to \$1.60. During the first nine months of 2009, the Company granted options to purchase a total of 491,927 shares of its common stock at exercise prices ranging from \$0.47 to \$0.95. 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 \$202,000 and \$648,000 for the three and nine-month periods ended September 30, 2010, respectively, and \$222,000 and \$688,000 for the three and nine-month periods ended September 30, 2009, respectively. As of September 30, 2010, there was approximately \$875,000 of total unrecognized compensation cost related to nonvested outstanding stock options that is expected to be recognized over a weighted average period of approximately 1.6 years.

The per share weighted average fair value of options granted during the first nine months of 2010 and 2009 were estimated as \$0.79 and \$0.39, respectively, on the date of grant using the Black-Scholes option pricing model based on the assumptions noted in the table below. Expected volatilities are based on the historical volatility of the Company's stock price. The weighted average expected life is based on both historical and anticipated employee behavior.

	September 30,	
	2010	2009
Risk-free interest rate	2.1%	1.9%
Annualized volatility	61.0%	88.0%
Weighted average expected life, in years	5.0	5.0
Expected dividend yield	0.0%	0.0%

Warrants to purchase a total of 17,824,959 shares of common stock were outstanding at September 30, 2010. The weighted average exercise price of the warrants was \$1.56.

The weighted average exercise price of the stock options and warrants outstanding at September 30, 2010 and 2009 was \$1.44 and \$1.46, respectively.

#### Stock Awards

The employment agreements with the Chief Executive Officer, Chief Financial Officer and other members of executive management include stock-based incentives under which the executives could be awarded up to approximately 1,530,000 shares of common stock upon the occurrence of various triggering events. Of these shares, 45,454 were awarded in 2010 and 180,681 were awarded prior to 2010. Compensation expense recorded in connection with awards considered probable of achievement was approximately \$13,300 and \$31,500 for the three and nine-month periods ended September 30, 2010, respectively, and approximately \$106,000 and \$122,000 for the three and nine-month periods ended September 30, 2009, respectively.

A total of 478,268 shares of common stock have been granted as stock awards to employees of the Company, of which 213,268 were granted in 2010. The majority of the stock awards vest over a three-year period, although 67,500 shares granted in 2010 vested immediately. A total of 239,104 of the shares granted are unvested as of September 30, 2010. Expense is recognized on a straight-line basis over the vesting period and is based on the fair value of the stock on the



grant date. The fair value of each stock award is determined based on the number of shares granted and the market price of the Company's common stock on the date of grant. Expense recognized in connection with these awards was approximately \$97,000 and \$182,000 for the three and nine-month periods ended September 30, 2010, respectively, and \$33,000 and \$58,000 for the three and nine-month periods ended September 30, 2009, respectively. The weighted average fair value of the shares granted in 2010 was \$1.34 per share.

In addition to the shares granted to employees, in the first nine months of 2010 and 2009 a total of 29,063 and 33,019 shares of common stock, respectively, were granted to certain directors in lieu of cash as part of annual compensation. 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. Expense recognized in connection with shares granted to directors was approximately \$11,600 and \$27,600 for the three and nine-month periods ended September 30, 2010, respectively, and \$4,400 and \$16,300 for the three and nine-month periods ended September 30, 2009, 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 of their effect was anti-dilutive totaled 25,225,596 and 26,204,250 at September 30, 2010 and 2009, respectively. The table below discloses the basic and diluted loss per common share.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Net loss applicable to common shares	\$ (1,631,400)	\$ (2,824,384)	\$ (4,792,597)	\$ (7,884,152)
Basic and diluted weighted average common shares outstanding	83,615,043	75,870,525	82,937,306	70,702,423
Basic and diluted net loss per common share	\$ (0.02)	\$ (0.04)	\$ (0.06)	\$ (0.11)

#### 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:

	September 30, 2010	December 31, 2009
United States of America	\$ 14,123,229	\$ 17,384,011
Switzerland	544,056	1,759,362
	\$ 14,667,285	\$ 19,143,373





Revenues by customer location are summarized as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
United States of America	\$ 1,500,552	\$ 1,091,268	\$ 4,746,888	\$ 3,148,668
Europe	1,557,820	519,142	4,513,015	2,475,080
Other	63,688	44,373	277,230	105,671
	\$ 3,122,060	\$ 1,654,783	\$ 9,537,133	\$ 5,729,419

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Ferring	\$ 1,557,819	\$ 497,943	\$ 4,473,920	\$ 2,075,717
Teva	1,290,478	776,373	3,953,783	2,024,105
Population Council	65,987	207,553	150,347	642,243

6. Comprehensive Loss

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Net loss	\$ (1,631,400)	\$ (2,824,384)	\$ (4,792,597)	\$ (7,884,152)
Change in cumulative translation adjustment	(41,977)	(3,061)	43,161	62,054
Comprehensive loss	\$ (1,673,377)	\$ (2,827,445)	\$ (4,749,436)	\$ (7,822,098)

7. Revenue Recognition Change

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



The Company elected to adopt ASU 2009-13 on a prospective basis, with retrospective application to January 1, 2009. The Company recorded the impact of adoption in the financial results for the three-months ended September 30, 2009. This accounting standard should have been applied retrospectively to the beginning of the year and the impact of adoption included in the first quarter financial results. The third quarter 2009 financial results have been revised to reflect this immaterial correction. The result of this correction is a decrease to total revenues in the third quarter of 2009 of \$386,389, an increase to gross profit of \$69,450, and a decrease to net loss applicable to common shares of \$69,450. This correction did not affect year-to-date total revenues, gross profit and net loss applicable to common shares, and did not affect quarter and year-to-date net loss per common share.

The table below reconciles the amounts for the three months ended September 30, 2009 as previously reported to the amounts as reported in the consolidated statement of operations after applying the immaterial correction.

	Three Months Ended September 30, 2009		
	As Previously Reported	Correction Adjustments	As Reported After Correction
Development revenue	\$ 382,788	\$ 88,889	\$ 293,899
Licensing revenue	658,276	297,500	360,776
Total revenue	2,041,172	386,389	1,654,783
Cost of development and licensing revenue	701,960	455,839	246,121
Total cost of revenue	1,212,194	455,839	756,355
Gross profit	828,978	69,450	898,428
Operating loss	(2,612,294)	69,450	(2,542,844)
Net loss	(2,893,834)	69,450	(2,824,384)
Net loss per common share	\$ (0.04 )		\$ (0.04 )

#### 8. New Accounting Pronouncements

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

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

Forward-Looking Statements

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

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

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

- our inability to compete successfully against new and existing competitors or to leverage our marketing capabilities and our research and development capabilities;
  - our ability to partner Anturol®;
- delays in product introduction and marketing or interruptions in supply;
  - a decrease in business from our major customers and partners;



- adverse economic and political conditions;
- our inability to obtain additional financing, reduce expenses or generate funds when necessary;
- our inability to attract and retain key personnel; and
- our inability to effectively market our services or obtain and maintain arrangements with our customers, partners and manufacturers.

In addition, you should refer to the “Risk Factors” section of our Annual Report on Form 10-K for the year ended December 31, 2009 for a discussion of other factors that may cause our actual results to differ materially from those described by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements contained in this report will prove to be accurate and, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material.

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

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

#### Overview

Antares Pharma, Inc. is an emerging pharma company that focuses on self-injection pharmaceutical products and technologies and topical gel-based products. Our subcutaneous and intramuscular injection technology platforms include Vibex™ disposable pressure-assisted auto injectors, Vision™ reusable needle-free injectors and disposable multi-use pen injectors. We currently view pharmaceutical and biotechnology companies as our primary customers.

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

In the gel-based area, we recently completed a successful pivotal Phase 3 trial for our lead product candidate, Anturool®, an oxybutynin ATD™ gel for the treatment of OAB, for which we expect to file an





NDA in 2010. Spending on this program in the first nine months of 2010 was approximately \$3,800,000, and we expect spending in 2010 to be approximately \$5,000,000. We also have a partnership with BioSante that includes LibiGel® (transdermal testosterone gel) in Phase 3 clinical development for the treatment of FSD, and Elestrin® (estradiol gel) currently marketed in the U.S for the treatment of moderate-to-severe vasomotor symptoms associated with menopause.

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

We incurred a net loss of \$4,792,597 for the nine-month period ended September 30, 2010 and we expect to report a net loss for the year ending December 31, 2010. We have not historically generated sufficient revenue to provide the cash needed to support our operations and have continued to operate primarily by raising capital and incurring debt. In order to better position ourselves to take advantage of potential growth opportunities and to fund future operations, during 2009, we raised additional capital and took steps to reduce our monthly cash obligations. We believe that the combination of our current cash and cash equivalents balance, our recent reductions in our monthly cash outflows, our projected product sales, product development revenue, license revenues, milestone payments and royalties will provide us with sufficient funds to support operations for at least the next 12 months.

## Results of Operations

### Three and Nine Months Ended September 30, 2010 and 2009

#### Revenues

Total revenues for the three and nine-month periods ended September 30, 2010 were \$3,122,060 and \$9,537,133, compared to revenues for the same prior-year periods of \$1,654,783 and \$5,729,419. Product revenue was \$1,654,215 and \$4,132,245 in the three and nine-month periods ended September 30, 2010, respectively, compared to \$923,155 and \$2,915,526, in the three and nine-month periods ended September 30, 2009, respectively. Our product revenue is generated from sales of our needle-free injector and disposable components and the increases were primarily due to increases in 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 launched our Tjet® needle-free device with their hGH Tev-Tropin® in the U.S. in August of 2009. Development revenue increased in the three and nine-month periods to \$401,723 and \$1,704,165, respectively, in 2010 compared to \$293,899 and \$1,362,632 in the same periods of the prior year. The increases were primarily due to a License, Development and Supply Agreement with Teva for a product containing epinephrine utilizing our Vibex™ auto injector technology. Licensing revenue also increased in the three and nine-month periods to \$582,817 and \$2,462,735, respectively, in 2010 from \$360,776 and \$1,166,362, respectively, in 2009. The increases were primarily due to recognition of revenue deferred in 2009 under an Exclusive License Agreement with Ferring, along with milestone payments received from Teva in the second quarter of 2010 and BioSante in the first quarter of 2010. Royalty revenue increased in the three and nine-month periods to \$483,305 and \$1,237,988, respectively, in 2010 from \$76,953 and \$284,899 in the same prior-year periods, primarily due to royalties received from Teva in connection with sales of their hGH Tev-Tropin®.



## Cost of Revenues and Gross Margins

The cost of product sales is related to our reusable needle free injector devices and disposable components. For the three and nine-month periods ended September 30, 2010, cost of product sales was \$798,532 and \$2,047,357, respectively, compared to \$510,234 and \$1,478,281 for the same periods of the prior year. Product gross margins were 52% and 45% in three-month periods ended September 30, 2010 and 2009, respectively, and were 50% and 49% for the nine-month periods ended September 30, 2010 and 2009, respectively. The product gross margin increase of 7% in the quarter consisted of approximately 4% due to a significant increase in sales in 2010 compared to 2009 while fixed overhead expenses in each respective period were relatively unchanged, and approximately 3% due to a shift in the mix of products sold. The increase in the nine-month period was primarily due to an increase in sales while fixed overhead expenses remained relatively constant.

The cost of development revenue consists primarily of direct external costs, some of which may have been previously incurred and deferred, along with labor costs and an allocation of certain overhead expenses based on actual costs and time spent related to revenue generating development arrangements. Cost of development revenue was \$280,982 and \$1,343,097 for the three and nine-month periods ended September 30, 2010, respectively, compared to \$246,121 and \$1,066,410 for the same prior-year periods. The increases in each period were due mainly to increases in development costs recognized related to a License, Development and Supply Agreement with Teva for a product containing epinephrine utilizing our auto injector technology.

## Research and Development

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

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

Although we are engaged in research and development activities involving each of our drug delivery platforms, over 75% of our total research and development expenses in each period were generated in connection with projects related to transdermal gel products, primarily Anturol®. Research and development expenses were \$2,332,712 and \$6,661,325 in the three and nine-month periods ended September 30, 2010, respectively, compared to \$2,004,921 and \$5,956,989 in the same periods of the prior year. The increases in the third quarter and first nine months of 2010 compared to the same periods of 2009 were due primarily to our Vibex MTX™ development program, along with increases in personnel costs due to the addition of two employees. Since the Vibex™ epinephrine program is associated with a License, Development and Supply Agreement with Teva, the costs have been deferred and are recognized as cost of revenue when the related revenue is recognized. Expenses incurred related to research and development activities in Switzerland decreased in the first nine months of 2010 compared to 2009 as a result of the Asset Purchase Agreement with Ferring at the end of 2009.

### Sales, Marketing and Business Development

Sales, marketing and business development expenses totaled \$204,750 and \$776,549 for the three and nine-month periods ended September 30, 2010, respectively, compared to \$173,797 and \$726,177 in the same prior-year periods. Decreases in consulting fees in 2010 were offset by increases in payroll expenses due to the addition of a senior level business development employee in January of this year.

### General and Administrative

General and administrative expenses totaled \$1,170,041 and \$3,509,630 in the three and nine-month periods ended September 30, 2010, respectively, compared to \$1,262,554 and \$3,715,519 in the same periods of the prior year. General and administrative expenses associated with the operations in Switzerland decreased significantly as a result of the transaction with Ferring at the end of 2009. These decreases were partially offset by increases in payroll expenses.

### Other Income (Expense)

Other income was \$33,557 and \$8,228 in the three and nine-month periods ended September 30, 2010, respectively, compared to expense of \$281,540 and \$670,195 in the same periods of the prior year. In 2010 other income consisted mainly of interest income and foreign exchange gains and losses. In 2009 other expense resulted primarily from interest expense related to our credit facility which was retired in the third quarter of 2009.

### Liquidity and Capital Resources

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

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

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

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



respect to the first tranche was forty-two months from February 2007 and (ii) with respect to the second tranche was thirty-six months from December 2007.

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

In the first nine months of 2010, we received proceeds of \$2,035,480 in connection with exercises of options and warrants to purchase shares of our common stock, which resulted in the issuance of 1,804,884 shares of our common stock.

At September 30, 2010, we had cash and cash equivalents of \$10,227,084. We believe that the combination of our current cash and cash equivalents balance and projected product sales, product development, license revenues, milestone payments and royalties will provide us with sufficient funds to support operations for at least the next 12 months. We do not currently have any bank credit lines. In the future, if we need additional financing and are unable to obtain such financing when needed, or obtain it on favorable terms, we may be required to curtail development of new products, limit expansion of operations or accept financing terms that are not as attractive as we may desire.

#### Cash Flows

##### Net Cash Used in Operating Activities

Net cash used in operating activities was \$5,325,799 and \$3,015,009 for the nine-month periods ended September 30, 2010 and 2009, respectively. Although the net loss decreased by \$3,091,555 to \$4,792,597 for the 2010 nine-month period from \$7,884,152 for the 2009 nine-month period, the cash used in 2009 was less than the cash used in 2010 primarily due to receipt of deferred revenue of \$4,076,375 from Teva in the third quarter of 2009.

##### Net Cash Used in Investing Activities

Net cash used in investing activities was \$128,837 and \$118,984 for the nine-month periods ended September 30, 2010 and 2009, respectively. Cash used for purchases of equipment, molds, furniture and fixtures was \$61,621 in 2010 compared to \$1,081 in 2009 and additions to patent rights were \$82,196 in 2010 compared to \$117,903 in 2009. In the first nine months of 2010, we received proceeds of \$14,980 from the sale of fully depreciated equipment that had been used at our Swiss location.

##### Net Cash Provided by Financing Activities

In the first nine months of 2010, net cash provided by financing activities consisted of proceeds from exercise of stock options and warrants of \$2,035,480. In the first nine months of 2009, net cash provided by financing activities of \$5,608,582 consisted of proceeds from the sale of common stock of \$10,527,650 and proceeds from exercise of warrants and stock options of \$95,322 less principal payments on long-term debt of \$5,014,390. The principal payments on long-term debt included a final payment of \$2,875,399 made in September 2009 when we used a portion of the proceeds from the sale of common stock and warrants to pay off the remaining balance of our credit facility.



## Research and Development Programs

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

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

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

As of September 30, 2010, we have incurred total external costs of approximately \$16,700,000 in connection with our Anturol® research and development, of which approximately \$3,800,000 was incurred in the first nine months of 2010. We expect total expenses for Anturol® to be approximately \$5,000,000 in 2010. The additional costs relate to the Phase III study closeout costs, safety study costs, NDA compilation costs and manufacturing related costs.

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

**Device Development Projects.** We are engaged in research and development activities related to our Vibex™ disposable pressure-assisted auto injectors and our disposable pen injectors. We have signed license agreements with Teva for our Vibex™ system for use with epinephrine and an undisclosed product and for our pen injector device for two undisclosed products. We are also developing a Vibex MTX™ autoinjector for delivery of methotrexate for treatment of rheumatoid arthritis. Our pressure-assisted auto injectors are designed to deliver drugs by injection from single-dose prefilled syringes. The auto injectors are in the advanced commercial stage of development. The disposable pen injector device is designed to deliver drugs by injection through needles from multi-dose cartridges. The disposable pen is in the early stage of development where devices are being evaluated in clinical studies. Our development programs consist of 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 second quarter of 2010 we entered into an agreement with Uman Pharma under which both companies will invest jointly to develop and commercialize Vibex MTX™. We will lead the clinical development program and FDA regulatory submissions, and will retain rights to commercialize the Vibex MTX™ product outside of Canada. Uman Pharma will perform formulation development and manufacturing activities to support the registration of Vibex MTX™ and supply methotrexate in prefilled syringes to us for the U.S. market. Uman Pharma received an exclusive license to commercialize the



Vibex MTX™ product in Canada. The companies intend to work together to commercialize the Vibex MTX™ product in other territories.

As of September 30, 2010, we have incurred total external costs of approximately \$5,900,000 in connection with research and development activities associated with our auto and pen injectors, of which approximately \$1,500,000 was incurred in the first nine months of 2010. As of September 30, 2010, approximately \$4,100,000 of the total costs of \$5,900,000 was initially deferred, of which approximately \$3,100,000 has been recognized as cost of sales and \$1,000,000 remains deferred. This remaining deferred balance will be recognized as cost of sales over the same period as the related deferred revenue will be recognized.

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

Other research and development costs. In addition to the Anturool® project, Teva related device development projects and our Vibex MTX™ development project, we incur direct costs in connection with other research and development projects related to our technologies and indirect costs that include salaries, administrative and other overhead costs of managing our research and development projects. Total other research and development costs were approximately \$2,200,000 for the nine months ended September 30, 2010.

#### Off-Balance Sheet Arrangements

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

#### Critical Accounting Policies

We have identified certain of our significant accounting policies that we consider particularly important to the portrayal of our results of operations and financial position and which may require the application of a higher level of judgment by management and, as a result, are subject to an inherent level of uncertainty. These policies are characterized as “critical accounting policies” and address revenue recognition and valuation of long-lived and intangible assets and goodwill, as more fully described under “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the year ended December 31, 2009. We have made no changes to these policies during the nine-month period ended September 30, 2010.

#### Item 3. QUANTITATIVE 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 fluctuations on intercompany balances. The effect of foreign exchange rate fluctuations on our financial results for the nine-month period ended September 30, 2010 was not material.

#### Item 4. CONTROLS AND PROCEDURES.

##### Disclosure Controls and Procedures

The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this report. 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, 2009, 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 EXHIBITS.

6.

(a) Exhibit Index

Exhibit No.	Description
31.1	Certificate of the Chief Executive Officer of Antares Pharma, Inc. required by Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended.
31.2	Certificate of the Chief Financial Officer of Antares Pharma, Inc. required by Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended.
32.1	Certificate of the Chief Executive Officer of Antares Pharma, Inc. required by Rule 13a-14(b) under the Securities Exchange Act of 1934, as amended.
32.2	Certificate of the Chief Financial Officer of Antares Pharma, Inc. required by Rule 13a-14(b) under the Securities Exchange Act of 1934, as amended.

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 10, 2010

/s/ Paul K. Wotton  
Dr. Paul K. Wotton  
President and Chief Executive Officer

November 10, 2010

/s/ Robert F. Apple  
Robert F. Apple  
Executive Vice President and Chief Financial Officer