

ANTARES PHARMA, INC.  
Form 10-Q  
November 12, 2009

---

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, 2009

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 [ ]

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.

Large accelerated filer Accelerated filer Non-accelerated filer [ ] Smaller reporting company x

(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 11, 2009, was 81,710,148.

---

---

---

ANTARES PHARMA, INC.

INDEX

	PAGE	
<b>PART I.</b>	<b>FINANCIAL INFORMATION</b>	
Item 1.	Financial Statements (Unaudited)	
	Consolidated Balance Sheets, as of September 30, 2009 and December 31, 2008	3
	Consolidated Statements of Operations for the three months and nine months ended September 30, 2009 and 2008	4
	Consolidated Statements of Cash Flows for the nine months ended September 30, 2009 and 2008	5
	Notes to Consolidated Financial Statements	6
Item 2.	Management’s Discussion and Analysis of Financial Condition and Results of Operations	15
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	24
Item 4.	Controls and Procedures	24
<b>PART II.</b>	<b>OTHER INFORMATION</b>	
Item 1A.	Risk Factors	25
Item 6.	Exhibits	25
	<b>SIGNATURES</b>	<b>26</b>

## PART I – FINANCIAL INFORMATION

## Item 1. FINANCIAL STATEMENTS.

ANTARES PHARMA, INC.  
CONSOLIDATED BALANCE SHEETS

	September 30, 2009	December 31, 2008
(Unaudited)		
<b>Assets</b>		
<b>Current Assets:</b>		
Cash and cash equivalents	\$ 15,556,291	\$ 13,096,298
Accounts receivable, less allowance for doubtful accounts of \$10,000	515,260	1,334,648
Inventories	326,830	182,038
Deferred costs	1,883,726	-
Prepaid expenses and other current assets	218,256	294,818
<b>Total current assets</b>	<b>18,500,363</b>	<b>14,907,802</b>
Equipment, molds, furniture and fixtures, net	500,261	1,788,163
Patent rights, net	709,777	644,856
Goodwill	1,095,355	1,095,355
Deferred costs	408,250	1,292,090
Other assets	177,697	183,139
<b>Total Assets</b>	<b>\$ 21,391,703</b>	<b>\$ 19,911,405</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current Liabilities:</b>		
Accounts payable	\$ 1,887,786	\$ 2,103,493
Accrued expenses and other liabilities	1,743,562	1,382,306
Notes payable and capital leases, net of discount of \$0 and \$121,762, respectively	44,689	2,705,070
Deferred revenue	4,643,410	1,179,820
<b>Total current liabilities</b>	<b>8,319,447</b>	<b>7,370,689</b>
Notes payable and capital leases, net of discount of \$0 and \$32,427, respectively	40,818	2,239,550
Deferred revenue – long term	2,102,917	3,057,901
<b>Total liabilities</b>	<b>10,463,182</b>	<b>12,668,140</b>
<b>Stockholders' Equity:</b>		
Common Stock: \$0.01 par; authorized 150,000,000 shares; 81,710,148 and 68,049,666 issued and outstanding at September 30, 2009 and December 31, 2008, respectively	817,101	680,496
Additional paid-in capital	139,296,954	127,926,205
Accumulated deficit	(128,475,997)	(120,591,845)
Accumulated other comprehensive loss	(709,537)	(771,591)

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

		10,928,521		7,243,265
Total Liabilities and Stockholders' Equity	\$	21,391,703	\$	19,911,405

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 Ended September 30,	
	2009	2008	2009	2008
<b>Revenue:</b>				
Product sales	\$ 923,155	\$ 995,710	\$ 2,915,526	\$ 2,679,096
Development revenue	382,788	99,730	1,362,632	309,828
Licensing revenue	658,276	173,451	1,166,362	621,745
Royalties	76,953	119,691	284,899	282,406
<b>Total revenue</b>	<b>2,041,172</b>	<b>1,388,582</b>	<b>5,729,419</b>	<b>3,893,075</b>
<b>Cost of revenue:</b>				
Cost of product sales	510,234	563,979	1,478,281	1,492,021
Cost of development and licensing revenue	701,960	31,999	1,066,410	90,714
<b>Total cost of revenue</b>	<b>1,212,194</b>	<b>595,978</b>	<b>2,544,691</b>	<b>1,582,735</b>
<b>Gross profit</b>	<b>828,978</b>	<b>792,604</b>	<b>3,184,728</b>	<b>2,310,340</b>
<b>Operating expenses:</b>				
Research and development	2,004,921	2,153,267	5,956,989	5,910,753
Sales, marketing and business development	173,797	347,326	726,177	1,352,556
General and administrative	1,262,554	1,318,597	3,715,519	4,641,765
	3,441,272	3,819,190	10,398,685	11,905,074
<b>Operating loss</b>	<b>(2,612,294)</b>	<b>(3,026,586)</b>	<b>(7,213,957)</b>	<b>(9,594,734)</b>
<b>Other income (expense):</b>				
Interest income	951	95,113	25,973	484,442
Interest expense	(270,157)	(239,255)	(629,947)	(797,314)
Foreign exchange gains (losses)	(5,532)	(7,309)	(33,703)	1,174
Other, net	(6,802)	(10,797)	(32,518)	(40,870)
	(281,540)	(162,248)	(670,195)	(352,568)
<b>Net loss</b>	<b>\$ (2,893,834)</b>	<b>\$ (3,188,834)</b>	<b>\$ (7,884,152)</b>	<b>\$ (9,947,302)</b>
<b>Basic and diluted net loss per common share</b>	<b>\$ (0.04)</b>	<b>\$ (0.05)</b>	<b>\$ (0.11)</b>	<b>\$ (0.15)</b>
<b>Basic and diluted weighted average common shares outstanding</b>	<b>75,870,525</b>	<b>67,979,666</b>	<b>70,702,423</b>	<b>66,979,848</b>

See accompanying notes to consolidated financial statements.

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

	For the Nine Months Ended	
	September 30,	
	2009	2008
Cash flows from operating activities:		
Net loss	\$ (7,884,152)	\$ (9,947,302)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	175,706	180,697
Stock-based compensation expense	884,379	837,008
Amortization of debt discount and issuance costs	206,519	211,270
Changes in operating assets and liabilities:		
Accounts receivable	823,715	(311,442)
Inventories	(144,792)	18,544
Prepaid expenses and other assets	40,274	303,553
Deferred costs	178,399	(699,045)
Accounts payable	(196,124)	1,131,629
Accrued expenses and other current liabilities	366,448	44,876
Deferred revenue	2,534,619	98,906
Net cash used in operating activities	(3,015,009)	(8,131,306)
Cash flows from investing activities:		
Proceeds from maturity of short-term investments	-	16,015,057
Purchases of equipment, molds, furniture and fixtures	(1,081)	(1,327,807)
Additions to patent rights	(117,903)	(83,452)
Net cash provided by (used in) investing activities	(118,984)	14,603,798
Cash flows from financing activities:		
Principal payments on long-term debt	(5,014,390)	(1,720,083)
Proceeds from sale of common stock	10,527,650	-
Proceeds from exercise of warrants and stock options	95,322	1,319,950
Net cash provided by (used in) financing activities	5,608,582	(400,133)
Effect of exchange rate changes on cash and cash equivalents	(14,596)	(2,945)
Net increase in cash and cash equivalents	2,459,993	6,069,414
Cash and cash equivalents:		
Beginning of period	13,096,298	9,758,924
End of period	\$ 15,556,291	\$ 15,828,338

See accompanying notes to consolidated financial statements



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

1. Description of Business

Antares Pharma, Inc. (“Antares,” the “Company” or “we”) is a product development company committed to improving pharmaceuticals through its patented drug delivery systems. Antares has multiple development partnerships with leading pharmaceutical companies. The Company’s products are designed to improve safety and efficacy profiles by minimizing dosing and reducing side effects while enabling improved patient compliance. Antares has three validated drug delivery systems: the ATDTM Advanced Transdermal Gel Delivery system; subcutaneous injection technology platforms, including Vibex™ disposable pressure-assisted auto injectors, Valeo™/Vision® reusable needle-free injectors, and disposable multi-use pen injectors; and Easy Tec™ oral disintegrating tablets. Two of the systems have generated FDA-approved products.

Our Parenteral Medicines (device) division is located in Minneapolis, Minnesota, where we develop and manufacture with partners novel pressure-assisted injectors, with and without needles, which allow patients to self-inject drugs. We make a reusable, needle-free, spring-action injector device known as the Medi-Jector VISION®, which is marketed for use with insulin and human growth hormone (“hGH”). We have had success in achieving distribution of our device for use with hGH through licenses to pharmaceutical partners, which has resulted in continuing market growth and, we believe, a high degree of customer satisfaction. Distribution of growth hormone injectors occurs in Europe, Japan and other Asian countries through our pharmaceutical company relationships. Recently, our needle-free injector was approved for use in the U.S. with Tev-Tropin®, which is the brand of hGH sold by our pharmaceutical partner Teva Pharmaceutical Industries Ltd. (“Teva”).

We have also developed variations of the needle-free injector by adding a very small hidden needle to a pre-filled, single-use disposable injector, called the Vibex™ pressure-assisted autoinjection system. This system is an alternative to the Medi-Jector Vision® system for use with injectable drugs in unit dose containers and is suitable for branded and branded generic injectables. We also developed a disposable multi-dose pen injector for use with standard multi-dose cartridges. We have entered into multiple licenses for these devices mainly in the U.S. and Canada with Teva.

Our Pharma division is located in Basel, Switzerland, where we develop pharmaceutical products utilizing our transdermal systems. Several licensing agreements with pharmaceutical companies of various sizes have led to successful clinical evaluation of our formulations. In 2006, the United States Food and Drug Administration (“FDA”) approved our first transdermal gel with a partner’s drug product for the treatment of vasomotor symptoms in post-menopausal women. We are also developing our own transdermal gel-based products for the market and have initiated a pivotal Phase III safety and efficacy trial for Anturool®, our oxybutynin transdermal gel product for overactive bladder.

Our corporate headquarters is 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 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, 2008. Operating results for the three and nine month periods ended September 30, 2009, are not necessarily indicative of the results that may be expected for the year ending December 31, 2009.

The Financial Accounting Standards Board ("FASB") sets generally accepted accounting principles ("GAAP") that the Company follows to ensure consistent reporting of its financial condition, results of operations, and cash flows. On July 1, 2009, the FASB issued FASB Accounting Standards Codification<sup>TM</sup>, sometimes referred to as the Codification or ASC. The Codification is a reorganization of previous authoritative GAAP, which consisted of thousands of standards established by a variety of standard setters, into 90 accounting topics. The FASB finalized the Codification effective for interim or annual reporting periods ending on or after September 15, 2009. The Codification does not change how the Company accounts for its transactions or the nature of related disclosures made. However, when referring to guidance issued by the FASB the Company will refer to topics in the ASC rather than prior FASB standards.

3. Fair Value of Financial Instruments

Cash equivalents are stated at cost, which approximates fair value.

4. Notes Payable and Capital Lease

In September 2009 the Company paid off the remaining principal balance of its credit facility. Interest expense related to the credit facility for the first nine months of 2009 was \$620,304, of which \$413,785 was interest paid in cash. The remaining interest expense of \$206,519 consisted of amortization of debt discount and debt issuance costs, of which \$72,400 was the unamortized balance of debt discount and debt issuance costs when the final payment was made.

In 2008 and 2007, the Company acquired lab equipment under capital lease agreements. The equipment and capital lease obligation were recorded at an amount of approximately \$100,000 in 2008 and \$115,000 in 2007. Principal payments of approximately \$44,689, \$26,770 and \$14,048 are due in each of the 12-month periods ended September 30, 2010, 2011 and 2012, respectively.

5. Stockholders' Equity

Common Stock

In July 2009, the Company raised gross proceeds of \$8,500,000 in a registered direct offering through the sale of shares of its common stock and warrants. The Company 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 will be exercisable six months after issuance at \$1.00 per share and will expire five years from the date of issuance.

In September 2009, the Company 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 will be exercisable six months after issuance at \$1.15 per share and will expire five years from the date of issuance.

Warrant and stock option exercises in the first nine months of 2009 and 2008 resulted in proceeds of \$95,322 and \$1,319,950, respectively, and in the issuance of 137,916 and 2,400,000 shares of common stock, respectively.

### Stock Options and Warrants

The Company accounts for employee stock compensation cost using the fair value method pursuant to the Compensation – Stock Compensation Topic of the FASB Codification (ASC 718), which requires a public entity to measure the cost of employee services received in exchange for the award of equity instruments based on the fair value of the award at the date of grant. The cost will be 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 grant 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 ranges from three to eleven years and the options vest in varying periods. As of September 30, 2009, the Plan had 1,679,930 shares available for grant. Stock option exercises are satisfied through the issuance of new shares.

A summary of stock option activity under the Plan as of September 30, 2009, 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, 2008	8,056,656	1.19		
Granted	491,927	0.60		
Exercised	(57,916 )	0.78		
Forfeited	(671,826 )	1.44		
Outstanding at September 30, 2009	7,818,841	1.13	6.5	1,886,368
Exercisable at September 30, 2009	5,655,537	1.31	5.5	881,047

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. During the first nine months of 2008 the Company granted options to purchase a total of 1,768,023 shares of its



common stock at exercise prices ranging from \$0.80 to \$1.02. 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 \$688,000 and \$814,000 for the first nine months of 2009 and 2008, respectively. As of September 30, 2009, there was approximately \$820,000 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 2009 and 2008 was estimated as \$0.39 and \$0.55, 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,	
	2009	2008
Risk-free interest rate	2.1%	3.2%
Annualized volatility	84.0%	79.0%
Weighted average expected life, in years	5.0	5.0
Expected dividend yield	0.0%	0.0%

Warrants to purchase a total of 18,385,409 shares of common stock were outstanding at September 30, 2009. The weighted average exercise price of the warrants was \$1.60.

The weighted average exercise price of the stock options and warrants outstanding at September 30, 2009 and 2008 was \$1.46 and \$1.65, respectively.

#### Stock Awards

The employment agreements with the Company's 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 1,380,000 shares of common stock upon the occurrence of various triggering events. Of these shares, 75,000 were awarded in the first nine months of 2009 and 45,454 were awarded prior to 2009. Compensation expense of approximately \$122,000 was recorded in the first nine months of 2009 in connection with performance-based awards.

In 2008, executive officers received stock awards totaling 180,000 shares of common stock. The stock awards vest in equal annual installments over a three-year period. 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 the stock awards 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 officer stock awards was approximately \$58,000 and \$20,000 in the first nine months of 2009 and 2008, respectively.



## 6. 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 26,204,250 and 25,211,609 at September 30, 2009 and 2008, respectively. The table below discloses the basic and diluted loss per common share.

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2009	2008	2009	2008
Net loss applicable to common shares	\$ (2,893,834)	\$ (3,188,834)	\$ (7,884,152)	\$ (9,947,302)
Basic and diluted weighted average common shares outstanding	75,870,525	67,979,666	70,702,423	66,979,848
Basic and diluted net loss per common share	\$ (0.04)	\$ (0.05)	\$ (0.11)	\$ (0.15)

## 7. Industry Segment and Operations by Geographic Areas

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

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

The Company has assets located in two countries as follows:

	September 30, 2009	December 31, 2008
United States of America	\$ 20,207,189	\$ 18,756,418
Switzerland	1,184,514	1,154,987
	\$ 21,391,703	\$ 19,911,405

Revenues by customer location are summarized as follows:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2009	2008	2009	2008
United States of America	\$ 1,477,658	\$ 199,468	\$ 3,148,668	\$ 669,587
Europe	519,142	1,079,212	2,475,080	2,926,837
Other	44,372	109,902	105,671	296,651
	\$ 2,041,172	\$ 1,388,582	\$ 5,729,419	\$ 3,893,075



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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2009	2008	2009	2008
Ferring				
Pharmaceuticals	\$ 497,943	\$ 955,830	\$ 2,075,717	\$ 2,521,515
Teva	1,162,762	14,285	2,024,105	60,714
Population Council	207,553	-	642,243	-

#### 8. Comprehensive Loss

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2009	2008	2009	2008
Net loss	\$ (2,893,834)	\$ (3,188,834)	\$ (7,884,152)	\$ (9,947,302)
Change in cumulative translation adjustment	(3,061 )	71,282	62,054	(36,702 )
Comprehensive loss	\$ (2,896,895)	\$ (3,117,552)	\$ (7,822,098)	\$ (9,984,004)

#### 9. New Accounting Pronouncements

Effective January 1, 2009, the Company adopted FASB ASC 805, "Business Combinations" (formerly Statement of Financial Accounting Standards ("SFAS") 141R). This establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any noncontrolling interest in the acquiree and the goodwill acquired in the business combination. ASC 805 also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. The Company's adoption of ASC 805 will apply prospectively to business combinations completed after January 1, 2009.

Effective January 1, 2009, the Company adopted the provisions of ASC 815, "Derivatives and Hedging," that were issued with Emerging Issues Task Force Issue 07-5, "Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock." This standard provides that an entity should use a two step approach to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock, including evaluating the instrument's contingent exercise and settlement provisions. The adoption of this pronouncement did not have an impact on the Company's consolidated financial statements.

The Company adopted the provisions of ASC 820-10, "Fair Value Measurements and Disclosures" (formerly SFAS No. 157), with respect to non-financial assets and liabilities effective January 1, 2009. This pronouncement defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. The adoption of ASC 820-10 did not have an impact on the Company's consolidated financial statements.

In May 2009, the FASB issued ASC 855, "Subsequent Events" (formerly SFAS 165), which establishes general standards of accounting for, and requires disclosure of, events that occur after the balance sheet date but before financial statements are issued or are available to be issued. The Company adopted the provisions of ASC 855 for the quarter ended June 30, 2009. The adoption of ASC 855 did not have an impact on the Company's consolidated financial statements.



In the third quarter of 2009, the Company elected early adoption of 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 based on the relative selling price of each deliverable. It also 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 more objective evidence of selling price is not available. The impact of adopting this pronouncement on the Company’s consolidated financial statements is discussed in Note 10.

#### 10. Revenue Recognition Change

As discussed in Note 9, the Company elected early adoption of ASU 2009-13. The Company elected to adopt ASU 2009-13 on a prospective basis, with retrospective application to January 1, 2009.

During the third quarter of 2009, the Company amended the License, Development and Supply Agreement with Teva originally entered into in July of 2006. Under the terms of the amendment, the Company received a payment of \$4,076,375 from Teva for tooling in process that had a carrying value of approximately \$1,200,000 and for an advance for the design, development and purchase of additional tooling and automation equipment, all of which is related to an undisclosed, fixed, single-dose, disposable injector product using the Company’s Vibex™ autoinjector platform. The changes to the agreement related to this payment along with various other changes to the original terms resulted in a material modification to the agreement. Because the agreement was materially modified, the accounting was re-evaluated under ASU 2009-13, and the provisions of ASU 2009-13 were applied as if they were applicable from inception of the agreement. The re-evaluation resulted in the agreement being separated into three units of accounting and resulted in changes to both the method of revenue recognition and the period over which revenue will be recognized. Under the new accounting, the original license fee and milestone payments received will be recognized as revenue over the development period, the \$4,076,375 payment received will be recognized as revenue as various tools and equipment are completed and delivered, and revenue during the manufacturing period will be recognized as devices are sold and royalties are earned. The accounting literature applicable at the time of the original agreement required the entire arrangement to be considered a single unit of accounting. Therefore, the payments received and the development costs incurred were being deferred and would have been recognized from the start of manufacturing through the end of the initial contract period. The amendment and adoption of ASU 2009-13 resulted in the recognition of revenue previously deferred of \$434,111 and the recognition of costs previously deferred of \$536,732 recorded on a cumulative catch-up basis in the third quarter of 2009. Also, tooling in process of approximately \$1,200,000 sold to Teva was reclassified from equipment, molds, furniture and fixtures to deferred costs. Adoption of ASU 2009-13 had no impact on the accounting for any of the Company’s other revenue arrangements containing multiple deliverables.

The table below shows amounts with adoption of ASU 2009-13 as reported in the Company’s consolidated statements of operations for the three and nine months ended September 30, 2009 and the amounts as they would have been reported without adoption of ASU 2009-13.

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

	Three Months Ended September 30, 2009		Nine Months Ended September 30, 2009	
	As Reported With Adoption Of ASU 2009-13	Without Adoption Of ASU 2009-13	As Reported With Adoption Of ASU 2009-13	Without Adoption Of ASU 2009-13
Development revenue	\$ 382,788	\$ 271,677	\$ 1,362,632	\$ 1,251,521
Licensing revenue	658,276	335,276	1,166,362	843,362
Total revenue	2,041,172	1,607,061	5,729,419	5,295,308
Cost of development and licensing revenue	701,960	165,228	1,066,410	529,678
Total cost of revenue	1,212,194	675,462	2,544,691	2,007,959
Gross profit	828,978	931,599	3,184,728	3,287,349
Operating loss	(2,612,294 )	(2,509,673 )	(7,213,957 )	(7,111,336 )
Net loss	(2,893,834 )	(2,791,213 )	(7,884,152 )	(7,781,531 )
Basic and diluted net loss per common share	\$ (0.04 )	\$ (0.04 )	\$ (0.11 )	\$ (0.11 )

The first table below shows amounts as reported in the Company's consolidated statements of operations for each quarter. The second table below is presented to show amounts for the implementation of ASU 2009-13 on January 1, 2009.

Amounts as reported:

	Three Months Ended		Six Months Ended
	March 31, 2009	June 30, 2009	June 30, 2009
Development revenue	\$ 680,170	\$ 299,674	\$ 979,844
Licensing revenue	425,707	82,379	508,086
Total revenue	2,026,403	1,661,844	3,688,247
Cost of development and licensing revenue	267,739	96,711	364,450
Total cost of revenue	711,855	620,642	1,332,497
Gross profit	1,314,548	1,041,202	2,355,750
Operating loss	(2,539,742 )	(2,061,921 )	(4,601,663 )
Net loss	(2,736,707 )	(2,253,611 )	(4,990,318 )
Basic and diluted net loss per common share	\$ (0.04 )	\$ (0.03 )	\$ (0.07 )

Amounts upon adoption of ASU 2009-13 on January 1, 2009:

	Three Months Ended		Six Months Ended
	March 31, 2009	June 30, 2009	June 30, 2009
Development revenue	\$ 746,837	\$ 321,896	\$ 1,068,733
Licensing revenue	697,707	107,879	805,586
Total revenue	2,365,070	1,709,566	4,074,636
Cost of development and licensing revenue	645,054	175,235	820,289

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

Total cost of revenue	1,089,170	699,166	1,788,336
Gross profit	1,275,900	1,010,400	2,286,300
Operating loss	(2,578,390 )	(2,092,723 )	(4,671,113 )
Net loss	(2,775,355 )	(2,284,413 )	(5,059,768 )
Basic and diluted net loss per common share	\$ (0.04 )	\$ (0.03 )	\$ (0.07 )

13

---

11. Subsequent Events

On November 6, 2009, the Company entered into an Asset Purchase Agreement (the “Purchase Agreement”) with Ferring Allschwil AG (“Ferring”). Pursuant to the terms and conditions of the Purchase Agreement, Ferring will purchase from the Company all of the assets, including equipment, fixtures, fittings and inventory, located at the Company’s research and development facility located in Allschwil, Switzerland (the “Facility”). Further pursuant to the terms and conditions of the Purchase Agreement, Ferring will assume the contractual obligations related to the Facility, including the real property lease for the Facility, and will continue to employ the employees working at the Facility.

Also on November 6, 2009, in tandem with the execution of the Purchase Agreement, the Company entered into an Exclusive License Agreement with Ferring, which agreement relates to a license under Antares’ patents and transfer of know-how for its transdermal gel technology for certain pharmaceutical products.

The Company evaluated all subsequent events through November 12, 2009, the date of filing of this 10-Q.

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 the product development of Anturool®;
  - 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, 2009;
- 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 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;
  - 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, 2008 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

We develop, produce and market pharmaceutical delivery products, including transdermal gels, oral disintegrating tablets and reusable needle-free and disposable pressure-assisted autoinjector and pen injector systems. In addition, we have several products and compound formulations under development. We have operating facilities in the U.S. and Switzerland. Our U.S. operation manufactures and markets reusable needle-free injection devices and related disposables, and develops disposable pressure-assisted autoinjector and pen injector systems. These operations, including all development and some U.S. administrative activities, are located in Minneapolis, Minnesota. We also have operations located in Basel, Switzerland, which consist of administration and facilities for the development of transdermal gels and oral disintegrating tablet products. Our Swiss operations focus principally on research, development and commercialization of pharmaceutical products and include a number of license agreements with pharmaceutical companies for the application of its drug delivery systems. Our corporate offices are located in Ewing, New Jersey.

We operate as a product development/drug delivery company in the broader pharmaceutical industry. Companies in this sector generally bring technology and know-how in the area of drug formulation and/or delivery to pharmaceutical product marketers through licensing and development agreements while actively pursuing development of their own products. We currently view pharmaceutical and biotechnology companies as our primary customers. We have negotiated and executed licensing relationships in the growth hormone segment (reusable needle-free devices in the U.S., Europe and Asia) and the transdermal gels segment (several development programs in place worldwide, including the U.S.



and Europe). In addition, we continue to support existing customers of our reusable needle-free devices for the home or alternate site administration of insulin in the U.S. market through distributors and have licensed both disposable auto and pen injection devices to Teva for use in undisclosed fields and territories. On June 29, 2009, we announced that Teva received approval of a Supplemental New Drug Application which added “needle-free injection” to its Tev-Tropin® brand human growth hormone drug label. Teva will market our needle-free device as the Tev-Tropin Tjet Injector system.

In the third quarter of 2009, we raised gross proceeds of \$11,500,000 through the sale of shares of our common stock and warrants. We used approximately \$3,000,000 of these proceeds to pay off the remaining balance of our credit facility. We also received a payment of \$4,076,375 from Teva for tooling in process that had a carrying value of approximately \$1,200,000 and for an advance for the design, development and purchase of additional tooling and automation equipment, all of which is related to an undisclosed, fixed, single-dose, disposable injector product using the Company’s Vibex™ autoinjector platform.

We incurred a net loss of \$7,884,152 for the nine month period ended September 30, 2009 and we expect to report a net loss for the year ending December 31, 2009. 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. Capital requirements will depend on numerous factors, including the status of collaborative arrangements and payments received under such arrangements, the progress of research and development programs, the receipt of revenues from sales of products and royalties and the ability to control costs.

#### Results of Operations

#### 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, valuation of long-lived and intangible assets and goodwill and accounting for debt and equity instruments, 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, 2008. Other than with respect to the revenue recognition critical accounting policy described below, we have made no changes to these policies during the nine month period ended September 30, 2009.

#### Revenue Recognition

In the third quarter of 2009, we elected early adoption of FASB 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 based on the relative selling price of each deliverable. It also 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 more objective evidence of selling price is not available. As discussed further in Note 10 to our consolidated financial statements, adoption of this accounting pronouncement resulted in the recognition of revenue previously deferred of \$434,111 and recognition of costs previously

deferred of \$536,732. As a result of adoption of ASU 2009-13, deferred revenues and deferred costs associated with one of our License, Development and Supply Agreements with Teva will be recognized as revenues and expenses earlier than would otherwise have occurred. We also expect revenues and expenses generated in connection with future multiple element arrangements will often be recognized over shorter periods than would have occurred prior to adoption of ASU 2009-13.

Three and Nine Months Ended September 30, 2009 and 2008

#### Revenues

Total revenues for the three and nine months ended September 30, 2009 were \$2,041,172 and \$5,729,419, respectively, compared to revenues for the same prior-year periods of \$1,388,582 and \$3,893,075, respectively.

Product revenue was \$923,155 and \$2,915,526 in the three and nine months ended September 30, 2009 compared to \$995,710 and \$2,679,096 in the three and nine months ended September 30, 2008. The decrease in the quarter was mainly due to a decrease in sales to Ferring, which was partially offset by sales to Teva in connection with Teva's launch of our Tjet needle-free device with their hGH Tev-Tropin®. In the year-to-date period the sales to Teva more than offset the decrease in sales to Ferring, resulting in an increase in product sales in 2009 compared to 2008 (see Note 7 to the consolidated financial statements). We believe Ferring sales fluctuations from quarter to quarter and the decrease from the prior year are driven mainly by Ferring inventory management practices and we expect product sales to Ferring to normalize in the first quarter of 2010.

Development revenue increased in the three and nine month periods ended September 30, 2009 to \$382,788 and \$1,362,632 compared to \$99,730 and \$309,828 in the same periods of the prior year. Licensing revenue increased in the three and nine month periods ended September 30, 2009 to \$658,276 and \$1,166,362 from \$173,451 and \$621,745 in the same periods of the prior year. In the third quarter of 2009, \$111,111 of development revenue and \$323,000 of licensing revenue recognized had been previously deferred and represents a portion of payments received from Teva under a License, Development and Supply Agreement for a product utilizing our autoinjector technology. This revenue was recognized as a result of adopting a new revenue recognition accounting standard, as described in Note 10 to the consolidated financial statements. The development revenue in 2009 related primarily to transdermal gel development work for Population Council and autoinjector development work for Teva. The development revenue in 2008 was generated from projects related to our transdermal gel, oral disintegrating tablet and autoinjector technologies. The licensing revenue increase in the quarter was primarily due to the revenue recognized after adoption of the new accounting standard and to a milestone payment received from Teva in connection with Teva's launch of our Tjet needle-free device with their hGH Tev-Tropin®. The licensing revenue for the nine month periods ended September 30, 2009 and 2008 included revenue recognized in connection with a previously deferred license fee related to our oral disintegrating tablet technology. In the first quarter of 2009, approximately \$338,000 of this previously deferred license fee was recognized after the customer terminated the agreement due to technical challenges with their drug molecule.

#### Cost of Revenues

The cost of product sales is related to reusable needle-free injector devices and disposable components. For the three and nine month periods ended September 30, 2009, cost of product sales was \$510,234 and \$1,478,281, respectively, compared to \$563,979 and \$1,492,021 for the same periods of the prior year.

Cost of product sales as a percentage of product sales was 55% and 57% in three-month periods ended September 30, 2009 and 2008, respectively, and was 51% and 56% for the nine month periods ended September 30, 2009 and 2008, respectively. Cost of product sales as a percentage of product sales was lower in 2009 than in 2008 mainly as a result of higher average selling prices in 2009 as compared to 2008. In addition, the nine month period ended September 30, 2008 included a write-down of inventory of approximately \$55,000.

The cost of development revenue consists of labor costs, direct external costs and an allocation of certain overhead expenses based on actual costs and time spent in revenue-generating activities. In the third quarter of 2009, we recognized \$536,732 of previously deferred development costs related to a License, Development and Supply Agreement with Teva for a product utilizing our autoinjector technology. These costs were recognized after adoption of the new revenue recognition accounting standard, as described in Note 10 to our consolidated financial statements. Development costs that were being deferred in connection with the Teva agreement were related to both licensing and development revenue that had been deferred. Excluding the development costs and revenue recognized in the third quarter related to the accounting change, cost of development revenue as a percentage of development revenue was 61% and 32% for the third quarters of 2009 and 2008, respectively, and was 40% and 29% for the nine month periods ended September 30, 2009 and 2008, respectively. The increases in each period were due mainly to development projects in 2009 that have a higher rate of direct external costs than the development projects in 2008 and to an increase in the overhead allocation rate used in 2009 compared to the rate used in 2008.

#### Research and Development

The majority of research and development expenses consist of external costs for studies and analysis activities, design work and prototype development. Over 75% of our total research and development expenses in each period were generated in connection with projects related to transdermal gel products, primarily the Phase III study of Anturool®. The balance of our research and development expenses are related primarily to development of our disposable Vibex™ autoinjector platform. Research and development expenses were \$2,004,921 and \$5,956,989 in the three and nine month periods ended September 30, 2009, respectively, compared to \$2,153,267 and \$5,910,753 in the same periods of the prior year.

#### Sales, Marketing and Business Development

Sales, marketing and business development expenses totaled \$173,797 and \$726,177 for the three and nine month periods ended September 30, 2009, respectively, compared to \$347,326 and \$1,352,556 in the same periods of the prior year. The decreases in each period were primarily due to reductions in payroll costs associated with headcount reductions and decreases in consulting fees.

#### General and Administrative

General and administrative expenses totaled \$1,262,554 and \$3,715,519 in the three and nine month periods ended September 30, 2009, respectively, compared to \$1,318,597 and \$4,641,765 in the same periods of the prior year. The decreases in each period were due mainly to decreases in payroll and patent related expenses.

#### Other Income (Expense)

Other expense was \$281,540 and \$670,195 in the three and nine month periods ended September 30, 2009, respectively, compared to expense of \$162,248 and \$352,568 in the same periods of the prior year. The increases were due primarily to decreases in interest income of \$94,162 in the three-month period and \$458,469 in the nine month period due to both a reduction in funds available for investment and a reduction in market interest rates received on invested funds. In the third quarter of 2009 a total of \$129,907 of interest expense was recognized in connection with the retirement of our credit facility. Excluding the interest related to the retirement of our credit facility, interest expense decreased \$99,005 and \$297,274 in the three and nine month periods ended September 30, 2009 as compared to the three and nine month periods ended September 30, 2008 due primarily to a lower credit facility principal balance.

#### Liquidity and Capital Resources

We have not historically generated, and do not currently generate, 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 the third quarter of 2009, we received net proceeds of \$10,527,650 through the sale of our common stock and warrants in two separate transactions. In July 2009, we raised gross proceeds of \$8,500,000 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 will be 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 will be exercisable six months after issuance at \$1.15 per share and will expire five years from the date of issuance.

In September 2009, we used proceeds from the second sale of common stock to pay off the remaining principal balance of our credit facility, making a final payment of \$2,932,907.

In the third quarter of 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. Teva purchased tooling in process from the Company that had a carrying value of approximately \$1,200,000 and paid the Company in advance for the design, development and purchase of additional tooling and automation equipment.

In addition, in the first nine months of 2009 we received proceeds of \$95,322 in connection with exercises of warrants and options to purchase shares of our common stock, which resulted in the issuance of 137,916 shares of our common stock. In 2008, we received proceeds of \$1,319,950 in connection with exercises of warrants to purchase shares of our common stock, which resulted in the issuance of 2,400,000 shares of our common stock.

We believe that the recent equity financings, the recent payment from Teva and projected product sales, product development, license revenues, milestone payments and royalties will provide sufficient funds to support operations for at least the next 12 months. We do not currently have any bank credit lines. In the

future, if we need additional financing and are unable to obtain such financing when needed, or obtain it on favorable terms, we may be required to curtail development of new products, limit expansion of operations or accept financing terms that are not as attractive as we may desire.

## Cash Flows

### Net Cash Used in Operating Activities

Net cash used in operating activities was \$3,015,009 and \$8,131,306 for the nine month periods ended September 30, 2009 and 2008, respectively. The decrease in cash used in operating activities was primarily due to receipt of \$4,076,375 from Teva in the third quarter of 2009 that was recorded as deferred revenue at September 30, 2009, and a reduction in the loss for the first nine months of 2009 compared to the first nine months of 2008 of \$2,063,150, partially offset by differences between years in the changes in operating assets and liabilities. Excluding the payment from Teva, the 2009 changes in operating assets and liabilities resulted in a use of cash of \$473,836, while in 2008 changes in operating assets and liabilities resulted in a source of cash of \$587,021. The 2009 use of cash was driven primarily by a decrease in deferred revenue of \$1,541,756, partially offset by a decrease in accounts receivable of \$823,715, while the 2008 source of cash was driven primarily by an increase in accounts payable of \$1,131,629, partially offset by an increase in deferred costs of \$699,045.

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

Net cash used in investing activities was \$118,984 in the first nine months of 2009, which consisted primarily of additions to patent rights. Net cash provided by investing activities was \$14,603,798 in the first nine months of 2008, which consisted of proceeds from maturity of short-term investments of \$16,015,057 that were partially offset by cash used for purchases of equipment of \$1,327,807 and patent rights of \$83,452. The equipment purchases in 2008 consisted primarily of tooling in process that was sold to Teva in the third quarter of 2009. In the third quarter of 2009, tooling in process of approximately \$1,200,000 was reclassified to development costs from equipment, molds, furniture and fixtures.

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

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. In the first nine months of 2008, net cash used in financing activities of \$400,133 consisted of proceeds from the exercise of warrants of \$1,319,950, less principal payments on long-term debt of \$1,720,083.

## Research and Development Programs

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

Anturool®. We are currently evaluating Anturool® for the treatment of overactive bladder (“OAB”). In the fourth quarter of 2007 we initiated 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 is expected to involve 600 patients (200 per arm) using two dose strengths (selected from the Phase II clinical trial) versus a placebo. Enrollment expanded to approximately sixty centers throughout the United States in 2009. In addition to the Phase III trial, we have 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, 2009, we have incurred total external costs of approximately \$11,700,000 in connection with our Anturol® research and development, of which approximately \$4,000,000 was incurred in the nine months ended September 30, 2009. We intend to seek a marketing partner to help fund the development of Anturol® and to complete the Phase III trial. To date, we have not entered into an agreement with a marketing partner. However, in the third quarter of 2009, we raised gross proceeds of \$11,500,000 through the sale of shares of our common stock and warrants. Because of the additional funding received, we will continue the Anturol® development program and expect total expenses for Anturol® to be approximately \$5,000,000 in 2009. Although the Phase III program for Anturol® will continue, the rate of progress of the program will be determined by the level of expenditures, which may be affected by the timing of engaging a marketing partner. If we cannot find a marketing partner, we may not have the resources to complete the development program and may have to delay or stop enrollment in the trial.

**Device Development Projects.** We are engaged in research and development activities related to our Vibex™ disposable pressure-assisted autoinjectors and our disposable pen injectors. We have signed license agreements with Teva for our Vibex™ system for two undisclosed products and for our pen injector device for two undisclosed products. Our pressure-assisted autoinjectors are designed to deliver drugs by injection from single-dose prefilled syringes. The autoinjectors are in the advanced commercial stage of development. The disposable pen injector device is designed to deliver drugs by injection through needles from multi-dose cartridges. The disposable pen is in the early stage of development where devices are being evaluated in clinical studies. Our development programs consist of determination of the device design, development of prototype tooling, production of prototype devices for testing and clinical studies, performance of clinical studies, and development of commercial tooling and assembly. As of September 30, 2009, we have incurred total external costs of approximately \$4,100,000 in connection with research and development activities associated with our auto and pen injectors, of which approximately \$700,000 was incurred in the nine months ended September 30, 2009. As of September 30, 2009, approximately \$3,000,000 of the total costs of \$4,100,000 had been deferred, of which approximately \$700,000 has been recognized as expense and \$2,300,000 remains deferred. This remaining deferred balance will be recognized as expense 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 2009, but the timing and extent of near-term future development will be dependent on certain decisions made by Teva. We recently 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 an undisclosed, fixed, single-dose, disposable injector product using our Vibex™ autoinjector platform. Although this payment and certain upfront and milestone payments have been received from Teva, there have been no commercial sales, 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 and 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 research and development projects. Total other research and development costs were approximately \$2,000,000 for the nine months ended September 30, 2009.

#### 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.

#### NEW ACCOUNTING PRONOUNCEMENTS

Effective January 1, 2009, we adopted FASB ASC 805, "Business Combinations" (formerly SFAS 141R). This establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any noncontrolling interest in the acquiree and the goodwill acquired in the business combination. ASC 805 also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. Adoption of ASC 805 will apply prospectively to business combinations completed after January 1, 2009.

Effective January 1, 2009, we adopted the provisions of ASC 815, "Derivatives and Hedging" that were issued with Emerging Issues Task Force Issue 07-5, "Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock." This provides that an entity should use a two step approach to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock, including evaluating the instrument's contingent exercise and settlement provisions. The adoption of this pronouncement did not have an impact on our consolidated financial statements.

We adopted the provisions of ASC 820-10, "Fair Value Measurements and Disclosures" (formerly SFAS No. 157), with respect to non-financial assets and liabilities effective January 1, 2009. This pronouncement defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. The adoption of ASC 820-10 did not have an impact on our consolidated financial statements.

In May 2009, the FASB issued ASC 855, "Subsequent Events" (formerly SFAS 165), which establishes general standards of accounting for, and requires disclosure of, events that occur after the balance sheet date but before financial statements are issued or are available to be issued. We adopted the provisions of ASC 855 for the quarter ended June 30, 2009. The adoption of ASC 855 did not have an impact on our consolidated financial statements.

In the third quarter of 2009, we elected early adoption of FASB 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 based on the relative selling price of each deliverable. It also 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 more objective evidence of selling price is not available. The impact of adopting this pronouncement is discussed in Note 10 to 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 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 our 2003 agreement with Ferring, to establish prices in U.S. dollars rather than Euros for certain products and effectively reducing our 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, 2009 was not material.

Item 4. CONTROLS AND PROCEDURES.

Disclosure Controls and Procedures

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

Internal Control over Financial Reporting

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

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



with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART II - OTHER INFORMATION

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, 2008, 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) E x h i b i t  
Index

Exhibit No.	Description
4.1	Form of Warrant to Purchase Common Stock (Incorporated by reference to Exhibit 4.1 of the registrant’s Current Report on Form 8-K filed on July 24, 2009).
4.2	Form of Warrant to Purchase Common Stock (Incorporated by reference to Exhibit 4.1 of the registrant’s Current Report on Form 8-K filed on September 18, 2009).
10.1	Placement Agent Agreement, dated July 23, 2009, between Antares Pharma, Inc., Cowen and Company, LLC, Oppenheimer & Co., Inc. and Ladenburg Thalman & Co. Inc. (Incorporated by reference to Exhibit 10.1 of the registrant’s Current Report on Form 8-K filed on July 24, 2009).
10.2	Form of Subscription Agreement, by and between Antares Pharma, Inc. and the investor party thereto (Incorporated by reference to Exhibit 10.2 of the registrant’s Current Report on Form 8-K filed on July 24, 2009).
10.3	Form of Subscription Agreement, by and between Antares Pharma, Inc. and the investor party thereto (Incorporated by reference to Exhibit 10.1 of the registrant’s Current Report on Form 8-K filed on September 18, 2009).
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.

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

- 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 12, 2009

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

November 12, 2009

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