ANTARES PHARMA, INC.
Form 10-Q
August 13, 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 June 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 o

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

Yes o No o

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

Large accelerated filer o	Accelerated filer o	Non –accelerated filer o	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 o No x

The number of shares outstanding of the registrant's Common Stock, $.01 par value, as of August 11, 2009, was 78,834,458.

ANTARES PHARMA, INC.

INDEX

			PAGE
PART I.		FINANCIAL INFORMATION	
	Item 1.	Financial Statements (Unaudited)	
		Consolidated Balance Sheets, as of June 30, 2009 and December 31, 2008	3
		Consolidated Statements of Operations for the three months and six months ended June 30, 2009 and 2008	4
		Consolidated Statements of Cash Flows for the six months ended June 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	14
	Item 3.	Quantitative and Qualitative Disclosures About Market Risk	22
	Item 4.	Controls and Procedures	23
PART II.		OTHER INFORMATION	
	Item 1A.	Risk Factors	24
	Item 4.	Submission of Matters to a Vote of Security Holders	24
	Item 6.	Exhibits	24
		SIGNATURES	25

PART I – FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS.

ANTARES PHARMA, INC.

CONSOLIDATED BALANCE SHEETS

	June 30, 2009 (Unaudited)	December 31, 2008
Assets		
Current Assets:		
Cash and cash equivalents	$7,037,369	$ 13,096,298
Accounts receivable, less allowance for doubtful accounts of $10,000	880,265	1,334,648
Inventories	307,012	182,038
Prepaid expenses and other current assets	287,617	294,818
Total current assets	8,512,263	14,907,802
Equipment, molds, furniture and fixtures, net	1,712,055	1,788,163
Patent rights, net	681,640	644,856
Goodwill	1,095,355	1,095,355
Deferred costs	1,256,031	1,292,090
Other assets	171,699	183,139
Total Assets	$13,429,043	$ 19,911,405
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$2,201,508	$ 2,103,493
Accrued expenses and other liabilities	1,357,589	1,382,306
Notes payable and capital leases, net of discount of $77,455 and $121,762, respectively	2,906,486	2,705,070
Deferred revenue	451,795	1,179,820
Total current liabilities	6,917,378	7,370,689
Notes payable and capital leases, net of discount of $5,275 and $32,427, respectively	845,693	2,239,550
Deferred revenue – long term	2,775,374	3,057,901
Total liabilities	10,538,445	12,668,140
Stockholders' Equity:		
Common Stock: $0.01 par; authorized 150,000,000 shares;		
68,209,458 and 68,049,666 issued and outstanding at		

June 30, 2009 and December 31, 2008, respectively	682,095	680,496
Additional paid-in capital	128,497,142	127,926,205
Accumulated deficit	(125,582,163)	(120,591,845)
Accumulated other comprehensive loss	(706,476)	(771,591)
	2,890,598	7,243,265
Total Liabilities and Stockholders' Equity	$13,429,043	$ 19,911,405

See accompanying notes to consolidated financial statements.

Index

ANTARES PHARMA, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2009	**2008**	**2009**	**2008**
Revenue:				
Product sales	$ 1,168,620	$ 945,017	$ 1,992,371	$ 1,683,386
Development revenue	299,674	106,101	979,844	210,098
Licensing revenue	82,379	225,321	508,086	448,294
Royalties	111,171	113,676	207,946	162,715
Total revenue	1,661,844	1,390,115	3,688,247	2,504,493
Cost of revenue:				
Cost of product sales	523,931	513,109	968,047	928,042
Cost of development revenue	96,711	21,600	364,450	58,715
Total cost of revenue	620,642	534,709	1,332,497	986,757
Gross profit	1,041,202	855,406	2,355,750	1,517,736
Operating expenses:				
Research and development	1,745,309	1,791,214	3,952,068	3,757,486
Sales, marketing and business development	216,863	574,566	552,380	1,005,230
General and administrative	1,140,951	1,635,763	2,452,965	3,323,168
	3,103,123	4,001,543	6,957,413	8,085,884
Operating loss	(2,061,921)	(3,146,137)	(4,601,663)	(6,568,148)
Other income (expense):				
Interest income	6,385	143,892	25,022	389,329
Interest expense	(164,557)	(268,791)	(359,790)	(558,059)
Foreign exchange gains (losses)	(21,219)	23,224	(28,171)	8,483
Other, net	(12,299)	(12,958)	(25,716)	(30,073)
	(191,690)	(114,633)	(388,655)	(190,320)
Net loss	(2,253,611)	(3,260,770)	(4,990,318)	(6,758,468)
Basic and diluted net loss per common share	$ (0.03)	$ (0.05)	$ (0.07)	$ (0.10)
Basic and diluted weighted average common shares outstanding	68,101,137	67,320,325	68,075,544	66,474,446

See accompanying notes to consolidated financial statements.

Index

ANTARES PHARMA, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	For the Six Months Ended June 30,	
	2009	**2008**
Cash flows from operating activities:		
Net loss	$ (4,990,318)	$ (6,758,468)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	114,364	118,569
Stock-based compensation expense	518,867	563,707
Amortization of debt discount and issuance costs	96,521	146,726
Changes in operating assets and liabilities:		
Accounts receivable	450,566	(132,037)
Inventories	(124,974)	(36,500)
Prepaid expenses and other current assets	27,359	312,166
Other assets	(6,271)	(591,840)
Accounts payable	135,355	1,297,501
Accrued expenses and other current liabilities	(11,449)	(149,761)
Deferred revenue	(964,554)	71,616
Net cash used in operating activities	(4,754,534)	(5,158,321)
Cash flows from investing activities:		
Proceeds from maturity of short-term investments	-	15,061,897
Purchases of equipment, molds, furniture and fixtures	(1,081)	(647,444)
Additions to patent rights	(85,920)	(51,794)
Net cash provided by (used in) investing activities	(87,001)	14,362,659
Cash flows from financing activities:		
Principal payments on long-term debt	(1,260,584)	(1,128,584)
Proceeds from exercise of warrants and stock options	53,667	1,319,950
Net cash provided by (used in) financing activities	(1,206,917)	191,366
Effect of exchange rate changes on cash and cash equivalents	(10,477)	22,368
Net increase (decrease) in cash and cash equivalents	(6,058,929)	9,418,072
Cash and cash equivalents:		
Beginning of period	13,096,298	9,758,924
End of period	$ 7,037,369	$ 19,176,996

See accompanying notes to consolidated financial statements

Index

ANTARES PHARMA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

1. Description of Business

Antares Pharma, Inc. ("Antares" or the "Company") 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 ATD™ 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. We have had success in achieving distribution of our device for use with hGH through licenses to pharmaceutical partners, and it 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 human growth hormone 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 auto injection 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 Anturol™, our oxybutynin transdermal gel product for overactive bladder.

The corporate headquarters is located in Ewing, New Jersey.

6

Index

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 six-month periods ended June 30, 2009, are not necessarily indicative of the results that may be expected for the year ending December 31, 2009.

3. Notes Payable and Capital Lease

In 2007, the Company received gross proceeds of $7,500,000 under a credit facility in tranches of $5,000,000 and $2,500,000. The per annum interest rate is 12.7% in the case of the first tranche and 11% in case of the second tranche. The maturity date (i) with respect to the first tranche is forty-two months from the first funding date and (ii) with respect to the second tranche is thirty-six months from the second funding date. The credit agreement is secured by all personal property of the Company, including all intellectual property. The credit agreement contains certain covenants and provisions, including, without limitation, covenants and provisions that:

- restrict the Company's ability to create or incur indebtedness (subject to enumerated exceptions);
- restrict the Company's ability to create or incur certain liens on its property (subject to enumerated exceptions);
- require the Company to use commercially reasonable efforts to maintain, on a consolidated basis, unrestricted cash and cash equivalents of at least $2,500,000;
- in certain circumstances, restrict the Company's ability to declare or pay any dividends on any shares of its capital stock, purchase or redeem any shares of its capital stock, return any capital to any holder of its equity securities or payment of certain bonuses; and
- restrict the Company's ability to make certain investments.

Total interest expense related to the credit facility for the first six months of 2009 was $353,168, of which $256,649 was interest paid in cash. The remaining interest expense of $96,519 consisted of amortization of debt discount and debt issuance costs. In connection with the credit facility, the Company issued warrants to purchase a total of 640,000 shares of common stock at an exercise price of $1.25. The fair value of the vested warrants was approximately $505,000, calculated using the Black-Scholes valuation model, and was recorded as an increase to equity and a decrease, or discount, to notes payable. The discount is being amortized and recorded as interest expense using the interest method over the term of the credit agreement.

Principal payments of $2,930,671 and $805,947 are due in each of the 12 month periods ended June 30, 2010 and 2011, respectively.

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 $53,270, $25,099 and $19,922 are due in each of the 12 month periods ended June 30, 2010, 2011 and 2012, respectively.

4. Fair Value of Financial Instruments

Cash equivalents are stated at cost, which approximates fair value. The fair value of notes payable was approximately $3,710,000 as compared to a carrying amount of $3,736,618 at June 30, 2009, estimated using interest rates that may be available to the Company for debt with similar remaining maturities.

5. Stockholders' Equity

Common Stock

Warrant and stock option exercises in the first six months of 2009 and 2008 resulted in proceeds of $53,667 and $1,319,950, respectively, and in the issuance of 85,333 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 Financial Accounting Standards Board Statement of Financial Accounting Standards No. 123R, "Share-Based Payment", 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 range from three to eleven years and they vest in varying periods. As of June 30, 2009, this plan had 1,792,877 shares available for grant. Stock option exercises are satisfied through the issuance of new shares.

8

Index

A summary of stock option activity under the Plan as of June 30, 2009, and the changes during the six-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	406,927	0.52		
Exercised	(5,333)	0.61		
Forfeited	(637,273)	1.45		
Outstanding at June 30, 2009	7,820,977	1.14	6.7	1,008,810
Exercisable at June 30, 2009	5,268,941	1.36	5.5	334,014

During the first six months of 2009 the Company granted options to purchase a total of 406,927 shares of its common stock at exercise prices ranging from $0.47 to $0.53. During the first six months of 2008 the Company granted options to purchase a total of 1,368,023 shares of its common stock at exercise prices ranging from $0.85 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 $466,000 and $558,000 for the first six months of 2009 and 2008, respectively. As of June 30, 2009, there was approximately $997,300 of total unrecognized compensation cost related to nonvested outstanding stock options that is expected to be recognized over a weighted average period of approximately 1.6 years.

The per share weighted average fair value of options granted during the first six months of 2009 and 2008 were estimated as $0.36 and $0.56 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.

	June 30, 2009		2008	
Risk-free interest rate	1.9	%	3.2	%
Annualized volatility	88.0	%	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 13,044,500 shares of common stock were outstanding at June 30, 2009. The weighted average exercise price of the warrants was $1.84.

Potentially dilutive stock options and warrants excluded from dilutive loss per share because their effect was anti-dilutive totaled 20,865,477 and 27,355,585 at June 30, 2009 and 2008, respectively.

9

Index

The weighted average exercise price of the stock options and warrants outstanding at June 30, 2009 and 2008 was $1.57 and $1.55, 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 1,380,000 shares of common stock upon the occurrence of various triggering events. Of these shares, 12,500 were awarded in the first six months of 2009 and 45,454 were awarded prior to 2009. Compensation expense of approximately $16,000 and $3,000 was recorded in the first six months of 2009 and 2008, respectively, 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 $25,000 and $10,000 in the first six 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. The table below discloses the basic and diluted loss per common share.

	Three Months Ended June 30,		**Six Months Ended June 30,**	
	2009	**2008**	**2009**	**2008**
Net loss applicable to common shares	$ (2,253,611)	$ (3,260,770)	$ (4,990,318)	$ (6,758,468)
Basic and diluted weighted avg common shares outstanding	68,101,137	67,320,325	68,075,544	66,474,446
Basic and diluted net loss per common share	$ (0.03)	$ (0.05)	$ (0.07)	$ (0.10)

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:

10

Index

The Company has assets located in two countries as follows:

	June 30, 2009	December 31, 2008
United States of America	$ 12,136,277	$ 18,756,418
Switzerland	1,292,766	1,154,987
	$ 13,429,043	$ 19,911,405

Revenues by customer location are summarized as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
United States of America	$ 886,257	$ 223,389	$ 1,671,011	$ 470,119
Europe	773,203	1,166,726	1,955,938	1,847,625
Other	2,384	-	61,298	186,749
	$ 1,661,844	$ 1,390,115	$ 3,688,247	$ 2,504,493

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Ferring	$ 752,932	$ 1,008,582	$ 1,577,774	$ 1,565,685
Teva	607,694	21,429	861,343	46,429
Population Council	41,448	-	434,690	-

8. Comprehensive Loss

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Net loss	$(2,253,611)	$(3,260,770)	$(4,990,318)	$(6,758,468)
Change in cumulative translation adjustment	(8,608)	30,780	65,115	(107,984)
Comprehensive loss	$(2,262,219)	$(3,229,990)	$(4,925,203)	$(6,866,452)

9. New Accounting Pronouncements

Effective January 1, 2009, the Company adopted FASB Statement of Financial Accounting Standards No. 141R (revised 2007), "Business Combinations" ("SFAS 141R"). SFAS 141R 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. SFAS 141R also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. The Company's adoption of SFAS 141R will apply prospectively to business combinations completed after January 1, 2009.

Effective January 1, 2009, the Company adopted the required provisions of FASB Staff Position No. FAS 142-3, "Determination of the Useful Life of Intangible Assets" ("FSP 142-3"). FSP

Index

142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FASB Statement No. 142, “Goodwill and Other Intangible Assets.” This guidance will be applied prospectively to intangible assets acquired on or after January 1, 2009. The adoption of FSP 142-3 had no impact on the Company’s consolidated financial statements.

Effective January 1, 2009, the Company adopted the provisions of Emerging Issues Task Force (“EITF”) Issue No. 07-1, “Accounting for Collaborative Arrangements” (“EITF 07-1”). EITF 07-1 provides guidance on how to determine whether an arrangement constitutes a collaborative arrangement, how costs incurred and revenue generated on sales to third parties should be reported by the participants in a collaborative arrangement, how payments made between participants in a collaborative arrangement should be characterized, and what participants should disclose in the notes to the financial statements about a collaborative arrangement. The adoption of EITF 07-1 had no impact on the Company’s consolidated financial statements.

In June 2008, the FASB issued EITF 07-5, “Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity’s Own Stock.” EITF 07-5 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. EITF 07-5 was effective as of January 1, 2009. The adoption of EITF 07-5 did not have a material impact on the Company’s consolidated financial statements.

The provisions of FASB Staff Position No. FAS 157-2, “Effective Date of FASB Statement No. 157” (“FSP 157-2”) delayed the effective date of the application of SFAS No. 157 to fiscal years beginning after November 15, 2008, for all nonfinancial assets and nonfinancial liabilities that are recognized or disclosed at fair value in the financial statements on a non-recurring basis. The adoption of FSP 157-2 had no impact on the Company’s consolidated financial statements.

In April 2009 the Financial Accounting Standards Board (“FASB”) issued Staff Position No. FAS 107-1, “Interim Disclosures about Fair Value of Financial Instruments” (“FSP 107-1”). FSP 107-1 expands the fair value disclosures required for all financial instruments within the scope of Statement of Financial Accounting Standards (“SFAS”) No. 107 to include interim periods. The Company adopted the provisions of FSP 107-1 for the quarter ended June 30, 2009. The adoption of FSP 107-1 is disclosed in Note 4 of the accompanying consolidated financial statements.

In May 2009, the FASB issued Statement No. 165, “Subsequent Events” (“FAS 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 FAS 165 for the quarter ended June 30, 2009. The adoption of FAS 165 did not have an impact on the Company’s consolidated financial statements.

In June 2009, the FASB issued SFAS No. 168, “The FASB Accounting Standards Codification™ and the Hierarchy of Generally Accepted Accounting Principles — A Replacement of FASB Statement No. 162” (“SFAS 168”). SFAS 168 establishes the “FASB Accounting Standard Codification™” (“Codification”) as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements in conformity with generally accepted accounting principles in the United States. All guidance contained in the Codification carries an equal level of authority. On the effective date of SFAS 168, the Codification will supersede all then-existing non-SEC accounting and reporting

standards. All other nongrandfathered non-SEC accounting literature not included in the Codification will become nonauthoritative. SFAS 168 is effective for financial statements issued for interim and annual periods ending after September 15, 2009. The adoption of SFAS 168 will not have an impact on the Company's consolidated financial statements.

10. Subsequent Events

In July of 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 5 years from the date of issuance.

In July of 2009, the Company received a payment from Teva in the amount of approximately $4,000,000 in connection with an amendment to a License, Development and Supply Agreement signed in July 2006. Teva purchased tooling 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.

The Company believes that the recent equity financing, 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.

The Company evaluated all subsequent events through August 13, 2009, the date of filing of this 10-Q.

Index

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

Forward-Looking Statements

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

- the impact of new accounting pronouncements;
- our expectations regarding the product development of Anturol™;
- our expectations regarding continued product development with Teva Pharmaceutical Industries, Ltd.;
- our plans regarding potential manufacturing and marketing partners;
- our future cash flow and our ability to service or repay our existing debt;
- our expectations regarding a net loss for the year ending December 31, 2009;
- the risks that our recurring losses, negative cash flows and inability to raise additional capital could threaten our ability to continue as a going concern; and
- our ability to raise additional financing, reduce expenses or generate funds in light of our current and projected level of operations and general economic conditions.

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

based on a combination of facts and factors currently known by us and projections of the future about which we cannot be certain. Many factors may affect our ability to achieve our objectives, including:

- our inability to compete successfully against new and existing competitors or to leverage our marketing capabilities and our research and development capabilities;

- delays in product introduction and marketing or interruptions in supply;

Index

- 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 read 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 auto injector 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 auto injector 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

Index

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 Pharmaceutical Industries, Ltd. ("Teva") for use in undisclosed fields and territories. On June 29, 2009, we announced with Teva 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.

We incurred a net loss of $4,990,318 for the six-month period ended June 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. We have made no changes to these policies during the six-month period ended June 30, 2009.

Three and Six Months Ended June 30, 2009 and 2008

Revenues

Total revenues for the three and six months ended June 30, 2009 were $1,661,844 and $3,688,247, compared to revenues for the same prior-year periods of $1,390,115 and $2,504,493. Product revenue increased to $1,168,620 and $1,992,371 in the three and six months ended June 30, 2009 compared to $945,017 and $1,683,386 in the three and six months ended June 30, 2008. The increases were primarily due to initial sales of needle-free injection devices and disposable components to Teva in anticipation of Teva's launch of our Tjet needle-free device with their human growth hormone Tev-Tropin®. Development revenue also increased in the three and six month periods to $299,674 and $979,844 in 2009 compared to $106,101 and $210,098 in the same periods of the prior year. The increases were primarily due to development work related to our transdermal gel and auto injector technologies. Licensing revenue decreased in the three month period to $82,379 in 2009 from $225,321 in 2008. The decrease was due primarily to the termination of a license agreement related to our oral disintegrating tablet technology in the first quarter of 2009 under which revenue was being recognized in 2008.

16

Index

Licensing revenue increased in the six month period to $508,086 in 2009 from $448,294 in 2008 primarily due to recognition in the first quarter of 2009 of approximately $338,000 of a previously deferred license fee related to our oral disintegrating tablet technology after the customer terminated the agreement due to technical challenges with their drug molecule.

Cost of Revenues

The cost of product sales are related to reusable needle free injector devices and disposable components. For the three and six month periods ended June 30, 2009, cost of product sales was $523,931 and $968,047, respectively, compared to $513,109 and $928,042 for the same periods of the prior year. Cost of product sales as a percentage of product sales was 45% and 54% in three month periods ended June 30, 2009 and 2008, respectively, and was 49% and 55% for the six month periods ended June 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 2008 periods 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. Cost of development revenue as a percentage of development revenue was 32% and 20% for the second quarters of 2009 and 2008 and was 37% and 28% for the six-month periods ended June 30, 2009 and 2008. The increases in each period were due mainly 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. While we are typically 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 $1,745,309 and $3,952,068 in the three and six-month periods ended June 30, 2009, respectively, compared to $1,791,214 and $3,757,486 in the same periods of the prior year. The increase in the first half of 2009 compared to the same period of 2008 was due primarily to the Phase III study of Anturol™.

Sales, Marketing and Business Development

Sales, marketing and business development expenses totaled $216,863 and $552,380 for the three and six-month periods ended June 30, 2009, respectively, compared to $574,566 and $1,005,230 in the same prior year periods. 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 $1,140,951 and $2,452,965 in the three and six-month periods ended June 30, 2009, respectively, compared to $1,635,763 and $3,323,168 in the same periods of the prior year. The decreases in each period were due mainly to decreases in payroll and patent related expenses.

Index

Other Income (Expense)

Other expense was $191,690 and $388,655 in the three and six-month periods ended June 30, 2009, respectively, compared to expense of $114,633 and $190,320 in the same periods of the prior year. The increases were due primarily to decreases in interest income of $137,507 in the three-month period and $364,307 in the six-month period due to both a reduction in funds available for investment and a reduction in market interest rates received on invested funds. The impact of the decreases in interest income was partially offset by decreases in interest expense of $104,234 in the three-month period and $198,269 in the six-month period primarily due to a lower notes payable 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 first half of 2009, we received proceeds of $53,667 in connection with exercises of warrants and options to purchase shares of our common stock, which resulted in the issuance of 85,333 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.

In 2007, we borrowed $7,500,000 under a note payable in two tranches of $5,000,000 and $2,500,000. The total remaining principal balance was $3,736,618 at June 30, 2009. The per annum interest rate under the note payable is 12.7% for the first tranche and 11% for the second tranche. The maturity dates under the note payable are (i) 42 months from the first funding date for the first tranche, and (ii) 36 months from the second funding date for the second tranche. We have scheduled debt payments of $2,930,671 and $805,947 for the 12 month periods ending June 30, 2010 and 2011. The amount payable under the note is secured by all of our personal property, including all intellectual property. The credit agreement governing the note payable contains certain covenants and provisions, including, without limitation, covenants and provisions that:

- restrict our ability to create or incur indebtedness (subject to enumerated exceptions);
- restrict our ability to create or incur certain liens on our property (subject to enumerated exceptions);
- in certain circumstances, require us to maintain, on a consolidated basis, unrestricted cash and cash equivalents of at least $2,500,000;
- in certain circumstances, restrict our ability to declare or pay any dividends on any shares of our capital stock, purchase or redeem any shares of our capital stock, return any capital to any holder of our equity securities or payment of certain bonuses; and
- restrict our ability to make certain investments.

On July 29, 2009 we closed on a registered direct offering in which 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 5 years from the date of issuance.

18

Index

In July of 2009, the Company received a payment from Teva in the amount of approximately $4,000,000 in connection with an amendment to a License, Development and Supply Agreement signed in July 2006. Teva purchased tooling 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.

We believe that the recent equity financing, 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 $4,754,534 and $5,158,321 for the six-month periods ended June 30, 2009 and 2008, respectively. Although the loss in the first half of 2009 was $1,768,150 less than the loss in the first half of 2008, the cash used in operating activities was only $403,787 less in 2009 than in 2008 due primarily to changes in operating assets and liabilities. In 2009 changes in operating assets and liabilities resulted in a use of cash of $493,968, while in 2008 changes in operating assets and liabilities resulted in a source of cash of $771,145. The 2009 use of cash was driven primarily by a decrease in deferred revenue of $964,554 partially offset by a decrease in accounts receivable of $450,566 while the 2008 source of cash was driven primarily by an increase in accounts payable of $1,297,501 partially offset by an increase in other assets of $591,840.

Net Cash Provided by (Used in) Investing Activities

Net cash used in investing activities was $87,001 in the first half of 2009, which consisted of additions to patent rights and purchases of equipment, molds, furniture and fixtures. Net cash provided by investing activities was $14,362,659 in the first half of 2008, which consisted of proceeds from maturity of short-term investments of $15,061,897 that were partially offset by cash used for purchases of equipment of $647,444 and patent rights of $51,794. The equipment purchases consisted primarily of tooling and production equipment related to commercial device deals.

Net cash Provided by (Used in) Financing Activities

In the first half of 2009, net cash used in financing activities of $1,206,917 consisted of principal payments on long-term debt of $1,260,584 and proceeds from exercise of warrants and stock options of $53,667. In the first half of 2008, net cash provided by financing activities of $191,366 consisted of proceeds from the exercise of warrants of $1,319,950 less principal payments on long-term debt of $1,128,584.

Research and Development Programs

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

Index

Anturol™. We are currently evaluating Anturol™ for the treatment of overactive bladder ("OAB"). In the fourth quarter of 2007 we initiated a Phase III pivotal trial designed toevaluate 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 June 30, 2009, we have incurred total external costs of approximately $10,400,000 in connection with our Anturol™ research and development, of which approximately $2,700,000 was incurred in the six months ended June 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 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. Because of the additional funding received, we will continue the Anturol™ development program and expect total expenses 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 auto injectors 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 auto injectors are designed to deliver drugs by injection from single dose prefilled syringes. The auto injectors are in the advanced commercial stage of development. The disposable pen injector device is designed to deliver drugs by injection through needles from multi-dose cartridges. The disposable pen is in the early stage of development where devices are being evaluated in clinical studies. Our development programs consist of determination of the device design, development of prototype tooling, production of prototype devices for testing and clinical studies, performance of clinical studies, and development of commercial tooling and assembly. As of June 30, 2009, we have incurred total external costs of approximately $2,400,000 in connection with research and development activities associated with our auto and pen injectors, of which approximately $140,000 was incurred in the six months ended June 30, 2009. As of June 30, 2009, $1,300,000 of the total costs have been deferred and will be recognized as an 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 approximately $4,000,000 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 $1,300,000 for the six months ended June 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 Statement of Financial Accounting Standards No. 141R (revised 2007), “Business Combinations” (“SFAS 141R”). SFAS 141R 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. SFAS 141R also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. Our adoption of SFAS 141R will apply prospectively to any business combinations completed after January 1, 2009.

Effective January 1, 2009, we adopted the required provisions of FASB Staff Position No. FAS 142-3, “Determination of the Useful Life of Intangible Assets” (“FSP 142-3”). FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FASB Statement No. 142, “Goodwill and Other Intangible Assets.” This guidance will be applied prospectively to our intangible assets acquired on or after January 1, 2009. The adoption of FSP 142-3 had no impact on our consolidated financial statements.

Effective January 1, 2009, we adopted the provisions of Emerging Issues Task Force (“EITF”) Issue No. 07-1, “Accounting for Collaborative Arrangements” (“EITF 07-1”). EITF 07-1 provides guidance on how to determine whether an arrangement constitutes a collaborative arrangement, how costs incurred and revenue generated on sales to third parties should be reported by the participants in a collaborative arrangement, how payments made between participants in a collaborative arrangement should be characterized, and what participants should disclose in the notes to the financial statements about a collaborative arrangement. The adoption of EITF 07-1 had no impact on our consolidated financial statements.

In June 2008, the FASB issued EITF 07-5, “Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity’s Own Stock.” EITF 07-5 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. EITF 07-5 was effective as of January 1, 2009. The adoption of EITF 07-5 did not have a material impact on our consolidated financial statements.

The provisions of FASB Staff Position No. FAS 157-2, “Effective Date of FASB Statement No. 157” (“FSP 157-2”) delayed the effective date of the application of SFAS No. 157 to fiscal years beginning after November 15, 2008, for all nonfinancial assets and nonfinancial liabilities that are recognized or disclosed at fair value in the financial statements on a non-recurring basis. The adoption of FSP 157-2 had no impact on our consolidated financial statements.

Index

In April 2009, the Financial Accounting Standards Board ("FASB") issued Staff Position No. FAS 107-1, "Interim Disclosures about Fair Value of Financial Instruments" ("FSP 107-1"). FSP 107-1 expands the fair value disclosures required for all financial instruments within the scope of Statement of Financial Accounting Standards No. 107 to include interim periods. We adopted the provisions of FSP 107-1 for the quarter ended June 30, 2009. The adoption of FSP 107-1 did not have a material impact on our consolidated financial statements.

In May 2009, the FASB issued Statement No. 165, "Subsequent Events" ("FAS 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 FAS 165 for the quarter ended June 30, 2009. The adoption of FAS 165 did not have a material impact on our consolidated financial statements.

In June 2009, the FASB issued SFAS No. 168, "The FASB Accounting Standards Codification™ and the Hierarchy of Generally Accepted Accounting Principles — A Replacement of FASB Statement No. 162" ("SFAS 168"). SFAS 168 establishes the "FASB Accounting Standard Codification™" ("Codification") as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements in conformity with generally accepted accounting principles in the United States. All guidance contained in the Codification carries an equal level of authority. On the effective date of SFAS 168, the Codification will supersede all then-existing non-SEC accounting and reporting standards. All other nongrandfathered non-SEC accounting literature not included in the Codification will become nonauthoritative. SFAS 168 is effective for financial statements issued for interim and annual periods ending after September 15, 2009. The adoption of SFAS 168 will not have a material impact on our consolidated financial statements.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Our primary market risk exposure is foreign exchange rate fluctuations of the Swiss Franc to the U.S. dollar as the financial position and operating results of our subsidiaries in Switzerland are translated into U.S. dollars for consolidation. Our exposure to foreign exchange rate fluctuations also arises from transferring funds to our Swiss subsidiaries in Swiss Francs. In addition, we have exposure to exchange rate fluctuations between the Euro and the U.S. dollar in connection with 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 six month period ended June 30, 2009 was not material.

Index

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 4. Submission of Matters to a Vote of Security Holders.

On May 15, 2009, the Company held an annual meeting of its stockholders. The following items were voted on at the meeting:

- Anton G. Gueth was elected to the Company's board of directors to serve until the 2012 annual meeting. With respect to the election of Mr. Gueth to the board of directors, there were 44,984,235 votes cast in favor of the election and 2,295,165 votes withheld. The terms of office of each of Dr. Jacques Gonella, Thomas J. Garrity, Dr. Rajesh C. Shrotriya, Dr. Paul K. Wotton and Dr. Leonard S. Jacob also continued after the meeting.
- The stockholders ratified the appointment of KPMG LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2009. There were 43,166,671 votes for the proposal, 4,004,127 votes against the proposal, 108,602 abstentions and zero broker non-votes.

Item 6. Exhibits.

(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.

Index

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.

August 13, 2009 /s/ Paul K. Wotton
Dr. Paul K. Wotton

President and Chief Executive Officer

August 13, 2009 /s/ Robert F. Apple
Robert F. Apple

Executive Vice President and Chief Financial Officer

Index