

ANTARES PHARMA, INC.
Form 10-Q
August 14, 2008

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, 2008**

Commission File Number 1-32302

ANTARES PHARMA, INC.

A Delaware Corporation
250 Phillips Blvd, Suite 290

IRS Employer Identification No. 41-1350192

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 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 "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one).

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company
(do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

The number of shares outstanding of the Registrant's Common Stock, \$.01 par value, as of August 13, 2008, was 67,979,666.

ANTARES PHARMA, INC.

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PART I – FINANCIAL INFORMATION*Item 1. FINANCIAL STATEMENTS***ANTARES PHARMA, INC.****CONSOLIDATED BALANCE SHEETS**

	June 30, 2008 (Unaudited)	December 31, 2007
Assets		
Current Assets:		
Cash and cash equivalents	\$ 19,176,996	\$ 9,758,924
Short-term investments	997,097	16,300,844
Accounts receivable, less allowance for doubtful accounts of \$10,000	653,814	486,887
Other receivables	248,452	20,181
Inventories	161,909	125,409
Prepaid expenses and other current assets	369,336	620,933
Total current assets	21,607,604	27,313,178
Equipment, molds, furniture and fixtures, net	1,745,787	467,676
Patent rights, net	618,896	572,174
Goodwill	1,095,355	1,095,355
Other assets	1,338,277	768,333
Total Assets	\$ 26,405,919	\$ 30,216,716
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	\$ 2,797,539	\$ 804,848
Accrued expenses and other liabilities	1,367,632	1,543,401
Notes payable and capital lease, net of discount of \$162,209 and \$199,060, respectively	2,292,953	2,109,385
Deferred revenue	1,250,519	964,673
Total current liabilities	7,708,643	5,422,307
Notes payable and capital lease, net of discount of \$82,730 and \$154,189, respectively	3,569,988	4,665,467
Deferred revenue	2,570,709	2,629,651
Total liabilities	13,849,340	12,717,425
Stockholders' Equity:		
Common Stock: \$0.01 par; authorized 150,000,000 shares; 67,979,666 and 65,529,666 issued and outstanding at June 30, 2008 and December 31, 2007, respectively	679,796	655,296

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Additional paid-in capital	127,329,893		125,430,653	
Accumulated deficit	(114,659,860)	(107,901,392)
Accumulated other comprehensive loss	(793,250)	(685,266)
	12,556,579		17,499,291	
Total Liabilities and Stockholders' Equity	\$26,405,919		\$ 30,216,716	

See accompanying notes to consolidated financial statements.

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ANTARES PHARMA, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

	For the Three Months Ended		For the Six Months Ended	
	June 30, 2008	2007	June 30, 2008	2007
Revenue:				
Product sales	\$ 945,017	\$ 1,068,723	\$ 1,683,386	\$ 1,694,810
Development revenue	106,101	460,358	210,098	791,054
Licensing revenue	225,321	145,913	448,294	1,994,081
Royalties	113,676	131,281	162,715	170,068
Total revenue	1,390,115	1,806,275	2,504,493	4,650,013
Cost of revenue:				
Cost of product sales	513,109	503,475	928,042	864,524
Cost of development revenue	21,600	64,256	58,715	170,759
Total cost of revenue	534,709	567,731	986,757	1,035,283
Gross profit	855,406	1,238,544	1,517,736	3,614,730
Operating expenses:				
Research and development	1,791,214	1,521,657	3,757,486	2,345,252
Sales, marketing and business development	574,566	430,461	1,005,230	816,334
General and administrative	1,635,763	1,484,882	3,323,168	3,115,689
	4,001,543	3,437,000	8,085,884	6,277,275
Operating loss	(3,146,137)	(2,198,456)	(6,568,148)	(2,662,545)
Other income (expense):				
Interest income	143,892	152,330	389,329	264,517
Interest expense	(268,791)	(230,260)	(558,059)	(310,838)
Foreign exchange gains (losses)	23,224	(12,736)	8,483	(28,847)
Other, net	(12,958)	(7,916)	(30,073)	11,094
	(114,633)	(98,582)	(190,320)	(64,074)
Net loss	(3,260,770)	(2,297,038)	(6,758,468)	(2,726,619)
Basic and diluted net loss per common share	\$ (0.05)	\$ (0.04)	\$ (0.10)	\$ (0.05)
Basic and diluted weighted average common shares outstanding	67,320,325	54,626,788	66,474,446	54,023,408

See accompanying notes to consolidated financial statements.

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ANTARES PHARMA, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	For the Six Months Ended June 30,	
	2008	2007
Cash flows from operating activities:		
Net loss	\$ (6,758,468)	\$ (2,726,619)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	118,569	119,483
Stock-based compensation expense	563,707	608,988
Amortization of prepaid license discount	-	98,124
Amortization of debt discount and issuance costs	146,726	86,959
Changes in operating assets and liabilities:		
Accounts receivable	(164,347)	135,380
Other receivables	32,310	(30,313)
Inventories	(36,500)	25,802
Prepaid expenses and other current assets	312,166	(106,137)
Other assets	(591,840)	(130,808)
Accounts payable	1,297,501	215,119
Accrued expenses and other current liabilities	(149,761)	22,394
Deferred revenue	71,616	(689,646)
Net cash used in operating activities	(5,158,321)	(2,371,274)
Cash flows from investing activities:		
Proceeds from maturity of short-term investments	15,061,897	5,585,464
Purchases of short-term investments	-	(10,200,990)
Purchases of equipment, molds, furniture and fixtures	(647,444)	(14,151)
Additions to patent rights	(51,794)	(43,106)
Net cash provided by (used in) investing activities	14,362,659	(4,672,783)
Cash flows from financing activities:		
Proceeds from notes payable	-	5,000,000
Capitalized debt issuance costs	-	(181,124)
Principal payments on long-term debt	(1,128,584)	-
Proceeds from exercise of warrants and stock options	1,319,950	2,292,692
Net cash provided by financing activities	191,366	7,111,568
Effect of exchange rate changes on cash and cash equivalents	22,368	(10,890)
Net increase in cash and cash equivalents	9,418,072	56,621
Cash and cash equivalents:		
Beginning of period	9,758,924	2,706,047
End of period	\$ 19,176,996	\$ 2,762,668

See accompanying notes to consolidated financial statements

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1. Description of Business

Antares Pharma, Inc. (“Antares” or the “Company”) is a specialty drug delivery/pharmaceutical company utilizing its experience and expertise in drug delivery systems to enhance the performance of established and developing pharmaceuticals. The Company currently has three established delivery platforms (1) transdermal gels, (2) oral disintegrating tablets, and (3) injection devices. The corporate headquarters is located in Ewing, New Jersey, with research and production facilities for parenteral products in Minneapolis, Minnesota, and research and development facilities for pharmaceuticals in Basel, Switzerland.

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, 2007. Operating results for the three and six-month periods ended June 30, 2008, are not necessarily indicative of the results that may be expected for the year ending December 31, 2008.

Short-Term Investments

All short-term investments are commercial paper or U.S. government agency discount notes that mature within one year of purchase and are classified as held-to-maturity because the Company has the positive intent and ability to hold the securities to maturity. The securities are carried at their amortized cost. At June 30, 2008 and December 31, 2007, the securities had a fair value of \$998,700 and \$16,332,927, respectively, and a carrying amount of \$997,097 and \$16,300,844, respectively. The fair value of the securities was determined using Level 1 inputs as defined in Statement of Financial Accounting Standards No. 157, “Fair Value Measurements”, which are quoted prices (unadjusted) in active markets for identical assets or liabilities.

3. Notes Payable and Capital Lease

In February 2007, the Company received gross proceeds of \$5,000,000 upon closing of the first tranche of a \$10,000,000 credit facility. In December 2007, the Company received gross proceeds of \$2,500,000, after amending the credit facility agreement to reduce the amount available to draw down in the second tranche from \$5,000,000 to \$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:

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- 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 2008 was \$544,605, of which \$397,880 was interest paid in cash. The remaining interest expense of \$146,725 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 agreement.

Principal payments of \$2,409,085, \$2,718,608 and \$805,947 are due in each of the twelve month periods ended June 30, 2009, 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 \$69,000, \$58,000, \$27,000 and \$20,000 are due in each of the twelve month periods ended June 30, 2009, 2010, 2011 and 2012, respectively.

4. Stock Based Compensation

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 equity compensation plan allows for the grants of options, restricted stock, stock units, stock appreciation rights and/or performance awards to officers, directors, consultants and employees. Under the Company's 2008 Equity Compensation 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, 2008, this plan had 3,160,142 shares available for grant. Stock option exercises are satisfied through the issuance of new shares.

ANTARES PHARMA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

A summary of stock option activity under the plan as of June 30, 2008, and the changes during the six-month period then ended is as follows:

			Weighted	
	Number of	Weighted	Average	Aggregate
	Shares	Average	Remaining	Intrinsic
		Exercise	Contractual	Value (\$)
		Price (\$)	Term (Years)	
Outstanding at December 31, 2007	5,582,391	1.58		
Granted	1,368,023	0.86		
Exercised	-	-		
Forfeited	(335,850)	2.25		
Outstanding at June 30, 2008	6,614,564	1.40	7.4	10,325
Exercisable at June 30, 2008	4,345,631	1.56	6.3	10,116

Total recognized compensation expense for stock options was approximately \$558,000 and \$520,000 for the first six months of 2008 and 2007, respectively. As of June 30, 2008, there was approximately \$1,600,000 of total unrecognized compensation cost related to nonvested outstanding stock options that is expected to be recognized over a weighted average period of approximately two years.

The per share weighted average fair value of options granted during the first six months of 2008 and 2007 were estimated as \$0.56 and \$1.14, 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. The weighted average expected life is based on both historical and anticipated employee behavior.

	June 30,			
	2008		2007	
Risk-free interest rate	3.2	%	4.7	%
Annualized volatility	79.0	%	109.0	%
Weighted average expected life, in years	5.0		5.0	
Expected dividend yield	0.0	%	0.0	%

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 1,605,000 shares of common stock upon the occurrence of various triggering events. Approximately 45,000 of the 1,605,000 shares were awarded prior to June 30, 2008, of which 22,727 were awarded to the Chief Financial Officer in the first half of 2008 in connection with a performance based award. In addition, certain members of executive management received stock grants in the second quarter of 2008 totaling 140,000 shares, which vest over a three year period. Expense of approximately \$20,000 and \$63,000 was recorded in the first half of 2008 and 2007, respectively, in connection with stock grants.

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ANTARES PHARMA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

5. Stockholders' Equity*Common Stock, Options and Warrants*

In July 2007, the Company received proceeds of \$14,742,671, net of offering costs of \$1,257,329, in a private placement of its common stock in which a total of 10,000,000 shares of common stock were sold at a price of \$1.60 per share. In connection with the private placement, the Company issued five-year warrants to purchase an aggregate of 3,800,000 shares of common stock with an exercise price of \$2.00 per share.

Warrant exercises in the first six months of 2008 resulted in proceeds of \$1,319,950 and in the issuance of 2,400,000 shares of common stock. Warrant and stock option exercises in the first six months of 2007 resulted in proceeds of \$2,292,692 and in the issuance of 2,187,317 shares of common stock.

During the first six months of 2008 and 2007, the Company granted options to purchase a total of 1,368,023 and 1,307,632 shares of its common stock, respectively. The options were granted to employees and members of the Company's board of directors at exercise prices ranging from \$0.85 to \$1.02 in 2008 and \$1.23 to \$1.65 in 2007. All options were granted at an exercise price that equaled the fair value of the Company's common stock on the date of the grant.

Warrants to purchase a total of 20,741,021 shares of common stock were outstanding at June 30, 2008. The weighted average exercise price of the warrants was \$1.59.

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		Six Months Ended	
	June 30, 2008	2007	June 30, 2008	2007
Net loss applicable to common shares	\$(3,260,770)	\$(2,297,038)	\$(6,758,468)	\$(2,726,619)
Basic and diluted weighted avg common shares outstanding	67,320,325	54,626,788	66,474,446	54,023,408

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Basic and diluted net loss per common share	\$ (0.05)	\$ (0.04)	\$ (0.10)	\$ (0.05)
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Potentially dilutive stock options and warrants excluded from dilutive loss per share because their effect was anti-dilutive totaled 27,355,585 and 24,934,412 at June 30, 2008 and 2007, respectively.

The weighted average exercise price of the stock options and warrants outstanding at June 30, 2008 and 2007 was \$1.55 and \$1.43, respectively.

7. Industry Segment and Operations by Geographic Areas

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

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

The Company has operating assets located in two countries as follows:

	June 30,	December 31,
	2008	2007
United States of America	\$ 25,223,346	\$ 28,432,486
Switzerland	1,182,573	1,784,230
	\$ 26,405,919	\$ 30,216,716

Revenues by customer location are summarized as follows:

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2008	2007	2008	2007
United States of America	\$ 223,389	\$ 260,866	\$ 470,119	\$ 2,249,615
Europe	1,166,726	1,430,710	1,847,625	2,172,545
Other	-	114,699	186,749	227,853
	\$ 1,390,115	\$ 1,806,275	\$ 2,504,493	\$ 4,650,013

The following summarizes significant customers comprising 10% or more of total revenue for the three months and six months ended June 30:

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2008	2007	2008	2007
Ferring	\$ 1,008,582	\$ 1,015,222	\$ 1,565,685	\$ 1,508,415
BioSante Pharmaceuticals, Inc.	59,325	44,232	111,082	1,838,062
Undisclosed	133,536	324,016	234,202	539,283

8. Comprehensive Loss

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	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2008	2007	2008	2007
Net loss	\$ (3,260,770)	\$ (2,297,038)	\$ (6,758,468)	\$ (2,726,619)
Change in cumulative translation adjustment	30,780	1,765	(107,984)	(8,833)
Comprehensive loss	\$ (3,229,990)	\$ (2,295,273)	\$ (6,866,452)	\$ (2,735,452)

9. New Accounting Pronouncements

Effective January 1, 2008, the Company adopted Emerging Issues Task Force (“EITF”) Issue No. 07-3, “Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities” (“EITF 07-3”). EITF 07-3 addresses the diversity that exists with respect to the accounting for the non-refundable portion of a payment made by a research and development entity for future research and development activities. Under EITF 07-3, an entity would defer and capitalize non-refundable advance payments made for research and development activities until the related goods are delivered or the related services are performed. The Company’s adoption of EITF 07-3 had no impact on the Company’s consolidated financial statements.

Effective January 1, 2008, the Company adopted FASB Statement of Financial Accounting Standards No. 159, “The Fair Value Option for Financial Assets and Financial Liabilities, Including an Amendment of FASB Statement No. 115” (“SFAS 159”), which permits an entity to measure certain financial assets and financial liabilities at fair value. The objective of SFAS 159 is to improve financial reporting by allowing entities to mitigate volatility in reported earnings caused by the measurement of related assets and liabilities using different attributes, without having to apply complex hedge accounting provisions. Under SFAS 159, entities that elect the fair value option (by instrument) will report unrealized gains and losses in earnings at each subsequent reporting date. The fair value option election is irrevocable, unless a new election date occurs. SFAS 159 establishes presentation and disclosure requirements to help financial statement users understand the effect of the entity’s election on its earnings, but does not eliminate disclosure requirements of other accounting standards. Assets and liabilities that are measured at fair value must be displayed on the face of the balance sheet. The Company chose not to elect the fair value option for its financial assets and liabilities existing at January 1, 2008, and did not elect the fair value option on financial assets and liabilities transacted in the six months ended June 30, 2008. Therefore, the adoption of SFAS 159 had no impact on the Company’s consolidated financial statements.

Effective January 1, 2008, the Company adopted FASB Statement of Financial Accounting Standards No. 157, “Fair Value Measurements” (“SFAS 157”) for financial assets and liabilities and any other assets and liabilities carried at fair value. This statement defines fair value, establishes a framework for measuring fair value and expands the related disclosure requirements. On February 12, 2008, the FASB delayed the effective date for non-financial assets and liabilities to fiscal years beginning after November 15, 2008; however, the effective date for financial assets and liabilities remained applicable to fiscal years beginning after November 15, 2007. The Company’s adoption of SFAS 157 had no impact on the Company’s consolidated financial statements, other than the disclosure in Note 2, and the Company is currently evaluating the potential impact of the delayed portion of this statement on its consolidated financial statements.

In December 2007, the FASB issued 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 provisions of SFAS 141R are effective beginning January 1, 2009. The

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Company's adoption of SFAS 141R will apply prospectively to business combinations completed on or after January 1, 2009.

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

Overview

The Company develops, produces and markets delivery based pharmaceutical products, including transdermal gels, oral disintegrating tablets and reusable needle-free and disposable pressure assisted auto injector and pen injector systems for both pharmaceutical partners and internal product candidates. The Company has operating facilities in the U.S. and Switzerland. The U.S. operation manufactures and markets reusable needle-free injection devices and related disposables, and develops disposable pressure assisted auto injectors, pen injector systems and injectable drugs for its delivery systems. These operations, including all development and some U.S. administrative activities, are located in Minneapolis, Minnesota. The Company also has operations located in Basel, Switzerland, which consists of administration and facilities for the development of transdermal gels and oral disintegrating tablet products. The 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. The Company's corporate offices are located in Ewing, New Jersey.

The Company operates as a specialty pharmaceutical 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 its own products. The Company currently views pharmaceutical and biotechnology companies as primary customers. The Company has negotiated and executed licensing relationships in growth hormone products (reusable needle-free devices in Europe and Asia) and in transdermal gels (several development programs in place worldwide, including the United States and Europe) and in oral disintegrating tablets. In addition, the Company continues to market reusable needle-free devices for the home or alternate-site administration of insulin in the U.S. market through distributors and has licensed both disposable and reusable injection devices in various territories to Teva Pharmaceuticals for use with human growth hormone and other undisclosed fields.

The Company incurred a net loss of \$6,758,468 for the six-month period ended June 30, 2008 and expects to report a net loss for the year ending December 31, 2008, as development costs related to bringing future generations of products to market continue. Long-term 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

The Company has identified certain of its significant accounting policies that it considers particularly important to the portrayal of the Company's results of operations and financial position and which may require the application of a higher level of judgment by the Company's management, and as a result are subject to an inherent level of uncertainty. These 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, each more fully described under "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's Annual Report on Form 10-K for the year ended December 31, 2007. The Company has made no changes to these policies during 2008.

Three and Six Months Ended June 30, 2008 and 2007

Revenues

Total revenues for the three and six months ended June 30, 2008 were \$1,390,115 and \$2,504,493, respectively, compared to revenues for the same prior-year periods of \$1,806,275 and \$4,650,013. The decrease in revenues in the three month period was primarily due to decreases in development revenue, which resulted primarily from reduction in and delays in revenue from agreements related to use of the Company's proprietary ATDTM gel technology and oral fast-melting tablet technology. The decrease in revenues in the six month period was impacted by the same factors contributing to the decrease in the second quarter, but the decrease was primarily due to a \$1,750,000 milestone payment received in the first quarter of 2007 under a sublicense arrangement related to an existing license agreement with BioSante Pharmaceuticals, Inc.

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, 2008, cost of product sales was \$513,109 and \$928,042, respectively, compared to \$503,475 and \$864,524 for the same periods of the prior year. Cost of product sales as a percentage of product sales was 54% and 47% in three month periods ended June 30, 2008 and 2007, respectively, and was 55% and 51% for the six month periods ended June 30, 2008 and 2007, respectively. The increase in 2008 was due primarily to 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. Cost of development revenue as a percentage of development revenue can fluctuate considerably between periods depending on the development projects in process. In some cases development projects are substantially labor based, resulting in relatively high margins, while in other cases development projects include a significant amount of external cost passed through to the customer at little or no markup, resulting in very low margins. Cost of development revenue as a percentage of development revenue was 20% and 14% for the second quarter of 2008 and 2007, respectively and was 28% and 22% for the six-month periods ended June 30, 2008 and 2007, respectively. The increases in each period were due mainly to a development milestone payment received and recognized in 2007 which had minimal related direct costs.

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Research and Development

Research and development expenses were \$1,791,214 and \$3,757,486 in the three and six-month periods ended June 30, 2008, respectively, compared to \$1,521,657 and \$2,345,252 in the same periods of the prior year. The increases in the second quarter and first half of 2008 compared to the same periods of 2007 were due primarily to a Phase III study of Anturol™ (oxybutynin gel) for the treatment of overactive bladder initiated in the second half of 2007.

Sales, Marketing and Business Development

Sales, marketing and business development expenses totaled \$574,566 and \$1,005,230 for the three and six-month periods ended June 30, 2008, respectively, compared to \$430,461 and \$816,334 in the same prior year periods. The increases in each period were primarily due to payroll related expenses and an increase in professional services related to market research.

General and Administrative

General and administrative expenses totaled \$1,635,763 and \$3,323,168 in the three and six-month periods ended June 30, 2008, respectively, compared to \$1,484,882 and \$3,115,689 in the same periods of the prior year. The increases in each period were due mainly to increases in patent related expenses. These increases were partially offset by decreases in various professional service expenses.

Other Income (Expense)

Other expense was \$114,633 and \$190,320 in the three and six-month periods ended June 30, 2008, respectively, compared to expense of \$98,582 and \$64,074 in the same periods of the prior year. The increase in each period was due primarily to an increase in interest expense resulting from notes payable that originated during the first and fourth quarters of 2007. The increase in interest expense in the first half of 2008 as compared to 2007 was partially offset by an increase in interest income resulting from higher cash and investment balances.

Liquidity and Capital Resources

The Company has not historically generated, and does not currently generate, enough revenue to provide the cash needed to support its operations, and has continued to fund capital needs in excess of revenue generated primarily by raising capital and incurring debt.

In the first half of 2008, the Company received proceeds of \$1,319,950 in connection with warrant exercises, which resulted in the issuance of 2,400,000 shares of common stock. In July of 2007, the Company received net proceeds of \$14,742,671 in a private placement of common stock in which a total of 10,000,000 shares of common stock were sold at a price of \$1.60 per share. In connection with the private placement, the Company issued five-year warrants to purchase an aggregate of 3,800,000 shares of common stock with an exercise price of \$2.00 per share. In

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2007, the Company also received proceeds of \$2,292,692 in connection with warrant and stock option exercises, which resulted in the issuance of 2,187,317 shares of common stock.

In February of 2007, the Company received gross proceeds of \$5,000,000 upon closing of the first tranche of a \$10,000,000 credit facility, to help fund working capital needs. In December of 2007, the Company received gross proceeds of \$2,500,000, after the Company amended the credit facility

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agreement to reduce the amount available to draw down in the second tranche from \$5,000,000 to \$2,500,000. The per annum interest rate is 12.7% in the case of the first tranche and 11% in the case of the second tranche. The maturity date (i) with respect to the first tranche 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;
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