ANTARES PHARMA, INC.
Form 10-Q
November 13, 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 September 30, 2008

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 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 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 November 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

	September 30, 2008 (Unaudited)	**December 31, 2007**
Assets		
Current Assets:		
Cash and cash equivalents	$15,828,338	$ 9,758,924
Short-term investments	-	16,300,844
Accounts receivable, less allowance for doubtful accounts of $10,000	1,021,382	486,887
Other receivables	83,946	20,181
Inventories	106,865	125,409
Prepaid expenses and other current assets	362,125	620,933
Total current assets	17,402,656	27,313,178
Equipment, molds, furniture and fixtures, net	1,763,492	467,676
Patent rights, net	597,989	572,174
Goodwill	1,095,355	1,095,355
Other assets	1,415,804	768,333
Total Assets	$22,275,296	$ 30,216,716
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$2,000,136	$ 804,848
Accrued expenses and other liabilities	1,528,267	1,543,401
Notes payable and capital lease, net of discount of $142,451 and $199,060, respectively	2,404,684	2,109,385
Deferred revenue	705,113	964,673
Total current liabilities	6,638,200	5,422,307
Notes payable and capital lease, net of discount of $54,813 and $154,189, respectively	2,899,727	4,665,467
Deferred revenue	3,025,039	2,629,651
Total liabilities	12,562,966	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 September 30, 2008 and December 31, 2007, respectively	679,796	655,296

Additional paid-in capital	127,603,196	125,430,653
Accumulated deficit	(117,848,694)	(107,901,392)
Accumulated other comprehensive loss	(721,968)	(685,266)
	9,712,330	17,499,291
Total Liabilities and Stockholders' Equity	$22,275,296	$ 30,216,716

See accompanying notes to consolidated financial statements.

ANTARES PHARMA, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2008	**2007**	**2008**	**2007**
Revenue:				
Product sales	$ 995,710	$ 904,495	$ 2,679,096	$ 2,599,305
Development revenue	99,730	115,527	309,828	906,581
Licensing revenue	173,451	104,210	621,745	2,098,291
Royalties	119,691	106,442	282,406	276,510
Total revenue	1,388,582	1,230,674	3,893,075	5,880,687
Cost of revenue:				
Cost of product sales	563,979	513,308	1,492,021	1,377,832
Cost of development revenue	31,999	38,332	90,714	209,091
Total cost of revenue	595,978	551,640	1,582,735	1,586,923
Gross profit	792,604	679,034	2,310,340	4,293,764
Operating expenses:				
Research and development	2,153,267	1,652,129	5,910,753	3,997,381
Sales, marketing and business development	347,326	369,625	1,352,556	1,185,959
General and administrative	1,318,597	1,346,657	4,641,765	4,462,346
	3,819,190	3,368,411	11,905,074	9,645,686
Operating loss	(3,026,586)	(2,689,377)	(9,594,734)	(5,351,922)
Other income (expense):				
Interest income	95,113	310,285	484,442	574,803
Interest expense	(239,255)	(228,997)	(797,314)	(539,835)
Foreign exchange gains (losses)	(7,309)	(9,605)	1,174	(38,452)
Other, net	(10,797)	6,962	(40,870)	18,055
	(162,248)	78,645	(352,568)	14,571
Net loss	$ (3,188,834)	$ (2,610,732)	$ (9,947,302)	$ (5,337,351)
Basic and diluted net loss per common share	$ (0.05)	$ (0.04)	$ (0.15)	$ (0.09)
Basic and diluted weighted average common shares outstanding	67,979,666	64,660,101	66,979,848	57,607,935

See accompanying notes to consolidated financial statements.

ANTARES PHARMA, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	For the Nine Months Ended September 30,	
	2008	**2007**
Cash flows from operating activities:		
Net loss	$ (9,947,302)	$ (5,337,351)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	180,697	185,956
Stock-based compensation expense	837,008	930,377
Amortization of prepaid license discount	-	147,186
Amortization of debt discount and issuance costs	211,270	153,297
Changes in operating assets and liabilities:		
Accounts receivable	(538,831)	(12,969)
Other receivables	227,389	(105,434)
Inventories	18,544	(32,399)
Prepaid expenses and other current assets	303,569	(201,538)
Other assets	(699,061)	(200,520)
Accounts payable	1,131,629	505,094
Accrued expenses and other current liabilities	44,876	161,892
Deferred revenue	98,906	(191,304)
Net cash used in operating activities	(8,131,306)	(3,997,713)
Cash flows from investing activities:		
Proceeds from maturity of short-term investments	16,015,057	8,275,674
Purchases of short-term investments	-	(18,929,240)
Purchases of equipment, molds, furniture and fixtures	(1,327,807)	(27,684)
Additions to patent rights	(83,452)	(104,690)
Net cash provided by (used in) investing activities	14,603,798	(10,785,940)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net	-	14,742,671
Proceeds from exercise of warrants and stock options	1,319,950	2,292,692
Proceeds from notes payable	-	5,000,000
Capitalized debt issuance costs	-	(181,125)
Principal payments on long-term debt	(1,720,083)	(131,956)
Net cash provided by (used in) financing activities	(400,133)	21,722,282
Effect of exchange rate changes on cash and cash equivalents	(2,945)	(9,728)
Net increase in cash and cash equivalents	6,069,414	6,928,901
Cash and cash equivalents:		
Beginning of period	9,758,924	2,706,047
End of period	$ 15,828,338	$ 9,634,948

See accompanying notes to consolidated financial statements

ANTARES PHARMA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

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 nine-month periods ended September 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. The Company held no short-term investments at September 30, 2008. At December 31, 2007, the securities had a fair value of $16,332,927 and a carrying amount of $16,300,844. Securities with fair values totaling $8,902,400 and $7,430,527 were determined using Level 1 and Level 2 inputs, respectively, at December 31, 2007. As defined in Statement of Financial Accounting Standards No. 157, “Fair Value Measurements,” Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities and Level 2 inputs include (i) quoted prices for similar assets or liabilities in active markets, (ii) quoted prices for identical or similar assets or liabilities in markets that are not active, (iii) inputs other than quoted prices that are observable for the asset or liability such as interest rates and yield curves observable at commonly quoted intervals, volatilities, prepayment speeds, loss severities, credit risks, and default rates, and (iv) inputs that are derived principally from or corroborated by observable market data by correlation or other means (market-corroborated inputs).

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

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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:

- 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 nine months of 2008 was $782,673, of which $571,404 was interest paid in cash and $211,269 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 $2,482,980, $2,634,293 and $241,106 are due in each of the twelve month periods ended September 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 $64,155, $42,618, $24,777 and $11,746 are due in each of the twelve month periods ended September 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 September 30, 2008, this plan had 2,880,142 shares available for grant. Stock option exercises are satisfied through the issuance of new shares.

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

	Number of Shares	Weighted Average Exercise Price ($)	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value ($)
Outstanding at December 31, 2007	5,582,391	1.58		
Granted	1,768,023	0.82		
Exercised	-	-		
Forfeited	(455,850)	1.97		
Outstanding at September 30, 2008	6,894,564	1.37	7.3	10,325
Exercisable at September 30, 2008	4,661,476	1.53	6.3	10,325

During the first nine months of 2008 and 2007, the Company granted options to purchase a total of 1,768,023 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 $0.80 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.

Total recognized compensation expense for stock options was approximately $814,000 and $823,000 for the first nine months of 2008 and 2007, respectively. As of September 30, 2008, there was approximately $1,437,000 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 nine months of 2008 and 2007 were estimated as $0.55 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 price. The weighted average expected life is based on both historical and anticipated employee behavior.

	September 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	%

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The employment agreements with members of executive management include stock-based incentives under which the executives could be awarded up to 1,930,000 shares of common stock upon the occurrence of various triggering events. Approximately 45,000 of the 1,930,000 shares were awarded prior to September 30, 2008, of which 22,727 were awarded in the first nine months of 2008 in connection with a performance based award. The remaining 1,885,000 shares are not probable of being awarded as of September 30, 2008. 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 $35,000 and $71,000 was recorded in the first nine months of 2008 and 2007, respectively, in connection with stock grants.

5. Stockholders' Equity

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 nine 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 nine months of 2007 resulted in proceeds of $2,292,692 and in the issuance of 2,187,317 shares of common stock.

Warrants to purchase a total of 18,317,045 shares of common stock were outstanding at September 30, 2008. The weighted average exercise price of the warrants was $1.65.

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 September 30,		**Nine Months Ended September 30,**	
	2008	**2007**	**2008**	**2007**
Net loss applicable to common shares	$(3,188,834)	$(2,610,732)	$(9,947,302)	$(5,337,351)
Basic and diluted weighted avg common shares outstanding	67,979,666	64,660,101	66,979,848	57,607,935
Basic and diluted net loss per common share	$(0.05)	$(0.04)	$(0.15)	$(0.09)

Potentially dilutive stock options and warrants excluded from dilutive loss per share because their effect was anti-dilutive totaled 25,211,609 and 28,734,412 at September 30, 2008 and 2007, respectively.

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The weighted average exercise price of the stock options and warrants outstanding at September 30, 2008 and 2007 was $1.57 and $1.50, 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:

	September 30, 2008	**December 31, 2007**
United States of America	$ 21,099,354	$ 28,432,486
Switzerland	1,175,942	1,784,230
	$ 22,275,296	$ 30,216,716

Revenues by customer location are summarized as follows:

	Three Months Ended September 30,		**Nine Months Ended September 30,**	
	2008	**2007**	**2008**	**2007**
United States of America	$ 199,468	$ 187,103	$ 669,587	$ 2,436,718
Europe	1,079,212	987,672	2,926,837	3,160,216
Other	109,902	55,899	296,651	283,753
	$ 1,388,582	$ 1,230,674	$ 3,893,075	$ 5,880,687

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

	Three Months Ended September 30,	**Nine Months Ended September 30,**

	2008	2007	2008	2007
Ferring Pharmaceuticals	$ 955,830	$ 910,688	$ 2,521,515	$ 2,419,103
BioSante Pharmaceuticals, Inc.	49,488	69,277	160,570	1,907,339
Undisclosed	102,696	86,953	336,897	626,236

8. Comprehensive Loss

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Net loss	$ (3,188,834)	$ (2,610,732)	$ (9,947,302)	$ (5,337,351)
Change in cumulative translation adjustment	71,282	(30,894)	(36,702)	(39,727)
Comprehensive loss	$ (3,117,552)	$ (2,641,626)	$ (9,984,004)	$ (5,377,078)

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 nine months ended September 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

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 of the Company's 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 a subsidiary of Teva Pharmaceutical Industries Ltd ("Teva") for use with human growth hormone and other undisclosed fields.

The Company incurred a net loss of $9,947,302 for the nine-month period ended September 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 Nine Months Ended September 30, 2008 and 2007

Revenues

Total revenues for the three and nine months ended September 30, 2008 were $1,388,582 and $3,893,075, respectively, compared to revenues for the same prior-year periods of $1,230,674 and $5,880,687. The increase in revenues in the three month period was primarily due to an increase in product sales to Ferring Pharmaceuticals ("Ferring"). The decrease in revenues in the nine-month period was primarily due to a one time $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 nine month periods ended September 30, 2008, cost of product sales was $563,979 and $1,492,021, respectively, compared to $513,308 and $1,377,832 for the same periods of the prior year. Cost of product sales as a percentage of product sales was 57% in three month periods ended September 30, 2008 and 2007, and was 56% and 53% for the nine-month periods ended September 30, 2008 and 2007, respectively. The increase in 2008 was due primarily to a write-down of inventory of approximately $100,000.

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 32% and 33% for the third quarter of 2008 and 2007, respectively, and was 29% and 23% for the nine-month periods ended September 30, 2008 and 2007, respectively. The increase in the nine-month period was due mainly to a development milestone payment received and recognized in 2007 which had minimal related direct

costs.

Research and Development

Research and development expenses were $2,153,267 and $5,910,753 in the three and nine-month periods ended September 30, 2008, respectively, compared to $1,652,129 and $3,997,381 in the same periods of the prior year. The increases in the third quarter and first nine months 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 $347,326 and $1,352,556 for the three and nine-month periods ended September 30, 2008, respectively, compared to $369,625 and $1,185,959 in the same prior year periods. The decrease in the quarter was primarily due to a reduction in legal fees partially offset by an increase in payroll related expenses. The increase in the nine-month period was primarily due to an increase in professional services related to market research.

General and Administrative

General and administrative expenses totaled $1,318,597 and $4,641,765 in the three and nine-month periods ended September 30, 2008, respectively, compared to $1,346,657 and $4,462,346 in the same periods of the prior year. The decrease in the third quarter was due mainly to decreases in payroll and patent related expenses, which were partially offset by increases in expenses associated with legal and professional services. The increase in the nine-month period was due mainly to increases in legal expenses of approximately $100,000 related to various contracts and employment issues and increases in patent related expenses of approximately $125,000 associated mainly with Anturol™.

Other Income (Expense)

Other expense was $162,248 and $352,568 in the three and nine-month periods ended September 30, 2008, respectively, compared to other income of $78,645 and $14,571 in the same periods of the prior year. The change from income to expense in the third quarter was primarily due to a decrease in interest income of $215,172 due to lower interest rates and lower cash and investment balances in 2008 as compared to 2007. The change from income to expense in the nine-month period was due primarily to an increase in interest expense of $257,479, resulting primarily from notes payable in place during all of 2008 that originated during the first and fourth quarters of 2007. The decrease in the nine-month period was also impacted by a decrease in interest income in the amount of $90,361.

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 nine months 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 the Company's 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 the Company's common stock with an exercise price of $2.00 per share. In 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 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;
- 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.

In connection with the credit facility, the Company issued warrants to purchase a total of 640,000 shares of its common stock at an exercise price of $1.25.

The Company believes that the combination of the recent debt and equity financings 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. For 2008, the Company believes capital expenditures may increase to approximately $1.5 million primarily in connection with commercial tooling activities. The Company does not currently have any bank credit lines. In the future, if the Company needs additional financing and is unable to obtain such financing when needed, or obtain it on favorable terms, the Company may be required to curtail development of new products, limit expansion of operations or accept financing terms that are not as attractive as the Company may desire.

Cash Flows

Operating Activities

Net cash used in operating activities was $8,131,306 and $3,997,713 for the nine-month periods ended September 30, 2008 and 2007, respectively. The difference between 2008 and 2007 was mainly the result of an increase in the amount of the Company’s net loss from $5,337,351 in the first nine months of 2007 to $9,947,302 in the first nine months of 2008. The net loss increase was primarily due to two factors: (i) in the first quarter of 2007, the Company received $1,750,000 under a sublicense arrangement related to an existing license agreement with BioSante Pharmaceuticals, Inc., and (ii) in the first nine months of 2008, there was a significant increase in product development

costs due to expenses associated with a

Phase III study of Anturol™ (oxybutynin gel) for the treatment of overactive bladder, initiated in the fourth quarter of 2007.

Investing Activities

Net cash provided by investing activities was $14,603,798 in the first nine months of 2008, which consisted of proceeds from maturity of short-term investments of $16,015,057 that were partially offset by cash used for purchases of equipment of $1,327,807 and patent rights of $83,452. The equipment purchases consisted primarily of tooling and production equipment related to commercial device deals. Cash used in investing activities of $10,785,940 in the first nine months of 2007 was primarily due to purchases of short-term investments of $18,929,240, which was partially offset by proceeds from the maturity of short-term investments of $8,275,674.

Financing Activities

In the first nine months of 2008, net cash used by financing activities of $400,133 consisted of proceeds from the exercise of warrants of $1,319,950 less principal payments on long-term debt of $1,720,083. In the first nine months of 2007, net cash provided by financing activities of $21,722,282 consisted primarily of proceeds from issuance of common stock of $14,742,671, proceeds from notes payable of $5,000,000 and proceeds from the exercise of warrants of $2,292,692.

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 nine months ended September 30, 2008. Therefore, the adoption of SFAS 159 had no impact on the Company’s consolidated financial statements.

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

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The Company’s 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 the Company’s subsidiaries in Switzerland are translated into U.S. dollars for consolidation. The Company’s exposure to foreign exchange rate fluctuations also arises from transferring funds to its Swiss subsidiaries in Swiss Francs. In addition, the Company has 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 of 2007, the Company amended the 2003 agreement with Ferring, establishing prices in U.S. dollars rather than Euros for certain products, reducing the exchange rate risk. Most of the Company’s sales and licensing fees are denominated in U.S. dollars, thereby significantly mitigating the risk of exchange rate fluctuations on trade receivables. The Company does not currently use derivative financial instruments to hedge against exchange rate risk. Because exposure increases as intercompany balances grow, the Company 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 three and nine-month periods ended September 30, 2008 was not material.

Typically, the Company’s short-term investments are U.S government agency discount notes or commercial paper that mature within six to twelve months of purchase. The market value of such investments fluctuates with current market interest rates. In general, as rates increase, the market value of a debt instrument is expected to decrease. The opposite is also true. To minimize such market risk, the Company has in the past and to the extent possible, will continue in the future, to hold such debt instruments to maturity at which time the debt instrument will be redeemed at its stated or face value. Due to the short duration and nature of these instruments, the Company does not believe there is a material exposure to interest rate risk related to its investment portfolio. The Company held no short-term investments at September 30, 2008.

The market risk sensitive instruments described above were entered into for purposes other than trading purposes. The Company held no market risk sensitive instruments entered into for trading purposes at September 30, 2008.

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 SEC'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 also is 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.

Cautionary Statement for Purposes of the "Safe Harbor" Provisions of the Private Securities Litigation Reform Act of 1995

Certain statements in this report are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. When used in this report, the words "may," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "intends," "potential" or "contin similar expressions are generally intended to identify forward-looking statements. Because these forward-looking statements involve risks and uncertainties, including those described in Item 1A of this report, actual results could differ materially from those expressed or implied by these forward-looking statements. These statements are only predictions. Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee future results, levels of activity, performance and/or achievements.

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Forward-looking statements represent the Company's expectations or beliefs concerning future events, including statements regarding the Company's current cash situation, need for additional capital, ability to continue operations, whether the Company will be successful in entering into new strategic relationships, the Company's ability to attract and retain customers, the Company's ability to adapt to changing technologies, the impact of competition and pricing pressures from actual and potential competitors with greater financial resources, the Company's ability to hire and retain competent employees, the Company's ability to protect and reuse its intellectual property, changes in general economic conditions, and other factors identified in the Company's filings with the Securities and Exchange Commission. The Company disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

PART II - OTHER INFORMATION

Item 1A. RISK FACTORS

The following "risk factors" contain important information about us and our business and should be read in their entirety. Additional risks and uncertainties not known to us or that we now believe to be not material could also impair our business. If any of the following risks actually occur, our business, results of operations and financial condition could suffer significantly. As a result, the market price of our common stock could decline and you could lose all of your investment. In this Section, the terms "we", "our" and "us" refer to Antares Pharma, Inc.

Risks Related to Our Operations

We have incurred significant losses to date, and there is no guarantee that we will ever become profitable.

We incurred a net loss of $9,947,302 for the nine months ended September 30, 2008 and incurred net losses of $8,578,939 and $8,099,846 in the fiscal years ended 2007 and 2006, respectively. In addition, we have accumulated aggregate net losses from the inception of business through September 30, 2008 of $117,848,694. The costs for research and product development of our drug delivery technologies along with marketing and selling expenses and general and administrative expenses have been the principal causes of our losses. We may not ever become profitable and if we do not become profitable your investment would be harmed.

We may need additional capital in the future in order to continue our operations.

In July of 2007, we completed a private placement of our common stock and warrants in which we received aggregate gross proceeds of $16,000,000. In February of 2007, we 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 we 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. We believe that the combination of the debt and equity financings and projected product sales, product development, license revenues, milestone payments and royalties will provide us with sufficient funds to support operations for at least the next 12 months. 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, accept financing terms that are not as attractive as we may desire or be forced to liquidate and close operations.

Long-term capital requirements will depend on numerous factors, including, but not limited to, the status of collaborative arrangements, the progress of research and development programs and the receipt of revenues from sales of products. Our ability to achieve and/or sustain profitable operations depends on a number of factors, many of which are beyond our control. These factors include, but are not limited to, the following:

- the demand for our technologies from current and future biotechnology and pharmaceutical partners;
- our ability to manufacture products efficiently, at the appropriate commercial scale, and with the required quality;
- our ability to increase and continue to outsource manufacturing capacity to allow for new product introductions;

- timing of our partners' development, regulatory and commercialization plans;
- the level of product competition and of price competition;
- our ability to develop, maintain or acquire patent positions;
- patient acceptance of our current and future products;
- our ability to develop additional commercial applications for our products;
- our limited regulatory and commercialization experience;
- our reliance on outside consultants;
- our ability to obtain regulatory approvals;
- our ability to attract the right personnel to execute our plans;
- our ability to control costs; and
- general economic conditions.

Over time we have changed our business model to be more commercially oriented by further developing our own products, we may not have sufficient resources to fully execute our plan.

We must make choices as to the drugs that we will combine with our transdermal gel, oral disintegrating tablet and disposable pressure assisted auto injector and reusable needle free technologies to move into the marketplace. We may not make the correct choice of drug or technologies when combined with a drug, which may not be accepted by the marketplace as we expected or at all. FDA approval processes for the drugs and drugs with devices may be longer in time and/or more costly and/or require more extended clinical evaluation than anticipated. Funds required to bring our own products to market may be more than anticipated or may not be available at all. We have limited experience in development of compounds, regulatory matters and bringing such products to market; therefore, we may experience difficulties in execution of development of internal product candidates.

We currently depend on a limited number of customers for the majority of our revenue, and the loss of any one of these customers could substantially reduce our revenue and impact our liquidity.

During the first nine months of 2008 we derived approximately 65% of our revenue from Ferring, and for the year ended December 31, 2007 we derived approximately 39% and 36% of our revenue from Ferring and BioSante, respectively. The revenue from Ferring was primarily product sales and royalties. The revenue from BioSante was milestone based and will likely not be recurring in the near future.

The loss of any of these customers or partners or reduction in our business activities could cause our revenues to decrease significantly, increase our continuing losses from operations and, ultimately, could require us to cease operating. If we cannot broaden our customer base, we will continue to depend on a few customers for the majority of our revenues. Additionally, if we are unable to negotiate favorable business terms with these customers in the future, our revenues and gross profits may be insufficient to allow us to achieve and/or sustain profitability or continue operations.

We have entered into four License, Development and/or Supply agreements for five potential products since November of 2005 with Teva or an affiliate of Teva. Although certain upfront and milestone payments have been received, 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.

In July 2007, we entered into a worldwide product development and license agreement with Jazz Pharmaceuticals. Under the agreement an upfront payment, development milestones, and royalties on product sales are due us under certain circumstances. If the development program conducted by Jazz is

not a success we may never receive any compensation other than the upfront payment earned at agreement execution and ongoing FTE based revenue.

In September 2007, we entered into a worldwide product development and license agreement with an undisclosed company using our oral disintegrating tablets to develop an unnamed opioid analgesic. Under the agreement an upfront payment, development milestones, and royalties on product sales are due us under certain circumstances. If the development program conducted by this company is not a success we may never receive any compensation other than the upfront payment earned at agreement execution and ongoing FTE based revenue.

If we or our third-party manufacturer are unable to supply Ferring with our devices pursuant to our current license agreement with Ferring, Ferring could own a fully paid up license for certain of our intellectual property.

Pursuant to our license agreement with Ferring, we licensed certain of our intellectual property related to our needle-free injection devices, including a license that allows Ferring to manufacture our devices on its own under certain circumstances for use with its human growth hormone product. In accordance with the license agreement, we entered into a manufacturing agreement with a third party to manufacture our devices for Ferring. If we or this third party are unable to meet our obligations to supply Ferring with our devices, Ferring would own a fully paid up license to manufacture our devices and to use and exploit our intellectual property in connection with Ferring’s human growth hormone product. In such event, we would no longer receive product sales and manufacturing margins from Ferring; however we would still receive royalties.

If we do not develop and maintain relationships with manufacturers of our drug candidates, then we may not successfully manufacture and sell our pharmaceutical products.

We do not possess the capabilities or facilities to manufacture commercial quantities of Anturol™, which is currently in development for overactive bladder, or any other of our future drug candidates. We must contract with manufacturers to produce Anturol™ according to government regulations. Our future development and delivery of our product candidates depends on the timely, profitable and competitive performance of these manufacturers. A limited number of manufacturers exist which are capable of manufacturing our product candidates. We may fail to contract with the necessary manufacturers or we may contract with manufactures on terms that may not be favorable to us. Our manufacturers must obtain FDA approval for their manufacturing processes, and we have no control over this approval process. Additionally, use of contract manufacturers exposes us to risks in the manufacturer's business such as their potential inability to perform from a technical, operational or financial standpoint.

We have contracted with a commercial supplier of pharmaceutical chemicals to supply us with the active pharmaceutical ingredient of oxybutynin for clinical quantities of Anturol™ in a manner that meets FDA requirements via reference of their DMF for oxybutynin. Additionally, we have contracted with Patheon, a manufacturing development company, to supply clinical quantities of Anturol™ in a manner that meets FDA requirements. The FDA has not approved the manufacturing processes of Patheon for Anturol™. Any failure by Patheon or our supplier of the active ingredient oxybutynin to achieve or maintain compliance with FDA standards could significantly harm our business since we do not currently have approved secondary manufacturers for Anturol™ gel or oxybutynin.

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If we do not develop and maintain relationships with manufacturers of our device products, then we may not successfully manufacture and sell our device products.

Our device manufacturing for our needle-free device has involved the assembly of products from machined stainless steel and composite components in limited quantities. Our planned future device business necessitates significant changes and additions to our contract manufacturing and assembly process due to the anticipated larger scale of manufacturing in our business plan. Our devices must be manufactured in compliance with regulatory requirements, in a timely manner and in sufficient quantities while maintaining quality and acceptable manufacturing costs. In the course of these changes and additions to our manufacturing and production methods, we may encounter difficulties, including problems involving scale-up, yields, quality control and assurance, product reliability, manufacturing costs, existing and new equipment and component supplies, any of which could result in significant delays in production.

We operate under a manufacturing agreement with Minnesota Rubber and Plastics (MRP), a contract manufacturing company, who manufactures and assembles our MJ7 devices and certain related disposable component parts. There can be no assurance that MRP will be able to continue to meet these regulatory requirements or our own quality control standards. Therefore, there can be no assurance that we will be able to successfully produce and manufacture our products. Any failure to do so would negatively impact our business, financial condition and results of operations. We will also continue to outsource manufacturing of our future disposable injection products to third parties. Such products will be price sensitive and may be required to be manufactured in large quantities, and we have no assurance that this can be done. Additionally, use of contract manufacturers exposes us to risks in the manufacturers' business such as their potential inability to perform from a technical, operational or financial standpoint.

We have contracted with Nypro, Inc (Nypro), an international manufacturing development company to commercialize our Vibex™ pressure assisted auto injector device in compliance with FDA QSR regulations. Any failure by Nypro to successfully manufacture the pressure assisted auto injector device in commercial quantities, and be in compliance with regulatory regulations, would have a negative impact on our future revenue expectations.

We rely on third parties to supply components for our products, and any failure to retain relationships with these third parties could negatively impact our ability to manufacture our products.

Certain of our technologies contain a number of customized components manufactured by various third parties. Regulatory requirements applicable to manufacturing can make substitution of suppliers costly and time-consuming. In the event that we could not obtain adequate quantities of these customized components from our suppliers, there can be no assurance that we would be able to access alternative sources of such components within a reasonable period of time, on acceptable terms or at all. The unavailability of adequate quantities, the inability to develop alternative sources, a reduction or interruption in supply or a significant increase in the price of components could have a material adverse effect on our ability to manufacture and market our products.

Our products have achieved only limited acceptance by patients and physicians, which continues to restrict marketing penetration and the resulting sales of more units.

Our business ultimately depends on patient and physician acceptance of our reusable needle-free injectors, disposable pressure assisted auto injectors, transdermal gels, oral disintegrating tablets and our

other drug delivery technologies as an alternative to more traditional forms of drug delivery, including injections using a needle, orally ingested drugs and more traditional transdermal patch products. To date, our device technologies have achieved only limited acceptance from such parties. The degree of acceptance of our drug delivery systems depends on a number of factors. These factors include, but are not limited to, the following:

- advantages over alternative drug delivery systems or similar products from other companies;
- demonstrated clinical efficacy, safety and enhanced patient compliance;
- cost-effectiveness;
- convenience and ease of use of injectors and transdermal gels;
- marketing and distribution support; and
- successful launch of our pharmaceutical partners products which utilize our devices.

Physicians may refuse to prescribe products incorporating our drug delivery technologies if they believe that the active ingredient is better administered to a patient using alternative drug delivery technologies, that the time required to explain use of the technologies to the patient would not be offset by advantages, or they believe that the delivery method will result in patient noncompliance. Factors such as patient perceptions that a gel is inconvenient to apply or that devices do not deliver the drug at the same rate as conventional drug delivery methods may cause patients to reject our drug delivery technologies. Because only a limited number of products incorporating our drug delivery technologies are commercially available, we cannot yet fully assess the level of market acceptance of our drug delivery technologies.

Various independent clinical studies have questioned the safety of hormone replacement therapy for menopausal women, and our female hormone replacement therapy business may suffer as a result.

In July 2002, the NIH halted a long-term study, known as the Women's Health Initiative, being conducted on oral female hormone replacement therapy ("HRT") using a combination of estradiol and progestin because the study showed an increased risk of breast cancer, heart disease and blood clots in women taking the combination therapy. The arm of the study using estrogen alone was stopped in March 2004 after the NIH concluded that the benefits of estrogen did not outweigh the stroke risk for women in this trial. The halted study looked at only one brand of oral combined HRT and of estrogen, and there is no information on whether brands with different levels of hormones would carry the same risk. In January 2003, the FDA announced that it would require new warnings on the labels of HRT products, and it advised patients to consult with their physicians about whether to continue treatment with continuous combined HRT and to limit the period of use to that required to manage post-menopausal vasomotor symptoms only. Subsequently, additional analysis from the NIH study has suggested a slight increase in the risk of cognitive dysfunction developing in patients on long-term combined HRT. The Million Women Study, conducted in the U.K., confirmed that current and recent use of HRT increases a woman's chance of developing breast cancer and that the risk increased with duration of use. Other HRT studies have found potential links between HRT and an increased risk of dementia and asthma. These results and recommendations impacted the use of HRT, and product sales have diminished significantly. We cannot predict whether our alternative route of transdermal administration of HRT products will carry the same risk as the oral products used in the study.

In 2006 the FDA approved Elestrin®, an estrogen gel developed by our partner BioSante for the treatment of vasomotor symptoms associated with menopause. The determination by the FDA of Elestrin's efficacy and safety may not impact the acceptance by physicians and patients of this product. In 2008 our partner BioSante reached agreement under a Special Protocol Assessment (SPA) for the

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Phase III program for LibiGel® for the treatment of female sexual dysfunction. The receipt of the SPA does not ensure the FDA will find LibiGel® safe or effective nor does it impact future acceptance by physicians and patients.

If transdermal gels do not achieve greater market acceptance, we may be unable to achieve profitability.

Because transdermal gels are not a widely understood method of drug delivery, our potential partners and consumers may have little experience with such products. Our assumption of higher value may not be shared by the potential partner and consumer. To date, transdermal gels have gained successful entry into only a limited number of markets. There can be no assurance that transdermal gels will ever gain market acceptance beyond these markets sufficient to allow us to achieve and/or sustain profitable operations in this product area.

Elestrin®, our transdermal estradiol gel, was launched by BioSante's marketing partner Bradley Pharmaceuticals in June 2007. To date, the market penetration of Elestrin® has been low. Additionally, Bradley was acquired by Nycomed in February 2008. Recently BioSante announced that it reacquired Elestrin® from Nycomed and that it has assumed all manufacturing, distribution and marketing responsibilities of Elestrin®.

We are developing Anturol, our oxybutynin gel for overactive bladder. We may seek a pharmaceutical partner to assist in the development and marketing of this potential product. However, we may be unsuccessful in partnering Anturol™ which may delay or affect the timing of the clinical program due to availability of resources.

We may be unable to successfully expand into new areas of drug delivery technology, which could negatively impact our business as a whole.

We intend to continue to enhance our current technologies. Even if enhanced technologies appear promising during various stages of development, we may not be able to develop commercial applications for them because

- the potential technologies may fail clinical studies;
- we may not find a pharmaceutical company to adopt the technologies;
- it may be difficult to apply the technologies on a commercial scale;
- the technologies may not be economical to market; or
- we may not receive necessary regulatory approvals for the potential technologies.

We have not yet completed research and development work or obtained regulatory approval for any technologies for use with any drugs other than insulin, human growth hormone and estradiol (Elestrin®). There can be no assurance that any newly developed technologies will ultimately be successful or that unforeseen difficulties will not occur in research and development, clinical testing, regulatory submissions and approval, product manufacturing and commercial scale-up, marketing, or product distribution related to any such improved technologies or new uses. Any such occurrence could materially delay the commercialization of such improved technologies or new uses or prevent their market introduction

entirely.

As health insurance companies and other third-party payors increasingly challenge the products and services for which they will provide coverage, our individual consumers may not be able to receive adequate reimbursement or may be unable to afford to use our products, which could substantially reduce our revenues and negatively impact our business as a whole.

Our injector device products are currently sold in the European Community ("EC") and elsewhere for use with human growth hormone and in the United States for use with insulin. In the case of human growth hormone, our products are generally provided to users at no cost by the drug supplier. In the United States the injector products are marketed and available for use with insulin and a sNDA has been recently filed seeking approval with human growth hormone.

Although it is impossible for us to identify the amount of sales of our products that our customers will submit for payment to third-party insurers, at least some of these sales may be dependent in part on the availability of adequate reimbursement from these third-party healthcare payors. Currently, insurance companies and other third-party payors reimburse the cost of certain technologies on a case-by-case basis and may refuse reimbursement if they do not perceive benefits to a technology's use in a particular case. Third-party payors are increasingly challenging the pricing of medical products and devices, and there can be no assurance that such third-party payors will not in the future increasingly reject claims for coverage of the cost of certain of our technologies. Insurance and third-party payor practice vary from country to country, and changes in practices could negatively affect our business if the cost burden for our technologies were shifted more to the patient. Therefore, there can be no assurance that adequate levels of reimbursement will be available to enable us to achieve or maintain market acceptance of our products or technologies or maintain price levels sufficient to realize profitable operations. There is also a possibility of increased government control or influence over a broad range of healthcare expenditures in the future. Any such trend could negatively impact the market for our drug delivery products and technologies.

Elestrin®, for which we receive royalties from our partner based on any commercial sales, was launched in June 2007. We have no way of knowing at this time if health insurance companies' reimbursement has negatively impacted patient use of Elestrin®.

The loss of any existing licensing agreements or the failure to enter into new licensing agreements could substantially affect our revenue.

One of our primary business pathways requires us to enter into license agreements with pharmaceutical and biotechnology companies covering the development, manufacture, use and marketing of drug delivery technologies with specific drug therapies. Under these arrangements, the partner companies typically assist us in the development of systems for such drug therapies and collect or sponsor the collection of the appropriate data for submission for regulatory approval of the use of the drug delivery technology with the licensed drug therapy. Our licensees may also be responsible for distribution and marketing of the technologies for these drug therapies either worldwide or in specific territories. We are currently a party to a number of such agreements, all of which are currently in varying stages of development. We may not be able to meet future milestones established in our agreements (such milestones generally being structured around satisfactory completion of certain phases of clinical development, regulatory approvals and commercialization of our product) and thus, would not receive the fees expected from such arrangements, related future royalties or product sales. Moreover, there can be no assurance that we will be successful in executing additional collaborative agreements or that existing or future agreements will result in increased sales of our drug delivery technologies. In such event, our business, results of operations and financial condition could be adversely affected, and our revenues and

gross profits may be insufficient to allow us to achieve and/or sustain profitability. As a result of our collaborative agreements, we are dependent upon the development, data collection and marketing efforts of our licensees. The amount and timing of resources such licensees devote to these efforts are not within our control, and such licensees could make material decisions regarding these efforts that could adversely affect our future financial condition and results of operations. In addition, factors that adversely impact the introduction and level of sales of any drug or drug device covered by such licensing arrangements, including competition within the pharmaceutical and medical device industries, the timing of regulatory or other approvals and intellectual property litigation, may also negatively affect sales of our drug delivery technology. We are relying on partners such as Ferring, Teva, Jazz, BioSante and an undisclosed partner in our device, gel and ODT platforms for future milestone, sales and royalty revenue. Any or all of these partners may never commercialize a product with our technologies or significant delays in anticipated launches of these products may occur. Any potential loss of anticipated future revenue could have an adverse affect on our business and the value of your investment.

The failure of any of our third-party licensees to develop, obtain regulatory approvals for, market, distribute and sell our products as planned may result in us not meeting revenue and profit targets.

Pharmaceutical company partners help us develop, obtain regulatory approvals for, manufacture and sell our products. If one or more of these pharmaceutical company partners fail to pursue the development or marketing of the products as planned, our revenues and profits may not reach expectations or may decline. We may not be able to control the timing and other aspects of the development of products because pharmaceutical company partners may have priorities that differ from ours. Therefore, commercialization of products under development may be delayed unexpectedly. Generally speaking, in the near term, we do not intend to have a direct marketing channel to consumers for our drug delivery products or technologies except through current distributor agreements in the United States for our insulin delivery device. Therefore, the success of the marketing organizations of our pharmaceutical company partners, as well as the level of priority assigned to the marketing of the products by these entities, which may differ from our priorities, will determine the success of the products incorporating our technologies. Competition in this market could also force us to reduce the prices of our technologies below currently planned levels, which could adversely affect our revenues and future profitability.

Additionally, there is no assurance that regulatory filings by our partners in the U.S. will be deemed sufficient by agencies equivalent to the FDA outside the U.S., potentially delaying non U.S. product launches.

If we cannot develop and market our products as rapidly or cost-effectively as our competitors, then we may never be able to achieve profitable operations.

Competitors in the overactive bladder, transdermal gel drug delivery, injector and other markets, some with greater resources and experience than us, may enter these markets, as there is an increasing recognition of a need for less invasive methods of delivering drugs. Additionally, there is an ever increasing list of competitors in the oral disintegrating tablet business. Our success depends, in part, upon maintaining a competitive position in the development of products and technologies in rapidly evolving fields. If we cannot maintain competitive products and technologies, our current and potential pharmaceutical company partners may choose to adopt the drug delivery technologies of our competitors. Companies that compete with our technologies include Watson Pharmaceuticals, Bioject Medical Technologies, Inc., Bentley Pharmaceuticals, Inc., Auxillium, BioChemics, Inc., Aradigm, Zogenix, Inc., Noven Pharmaceuticals, Inc., NovaDel Pharma Inc., Columbia Laboratories, Inc., Laboratoires Besins-

Iscovesco, MacroChem Corporation, NexMed, Inc. and The Medical House, along with other companies. We also compete generally with other drug delivery, biotechnology and pharmaceutical companies engaged in the development of alternative drug delivery technologies or new drug research and testing. Many of these competitors have substantially greater financial, technological, manufacturing, marketing, managerial and research and development resources and experience than we do, and, therefore, represent significant competition.

Additionally, new drug delivery technologies are mostly used only with drugs for which other drug delivery methods are not possible, in particular with biopharmaceutical proteins (drugs derived from living organisms, such as insulin and human growth hormone) that cannot currently be delivered orally or transdermally. Transdermal patches and gels are also used for drugs that cannot be delivered orally or where oral delivery has other limitations (such as high first pass drug metabolism, meaning that the drug dissipates quickly in the digestive system and, therefore, requires frequent administration). Many companies, both large and small, are engaged in research and development efforts on less invasive methods of delivering drugs that cannot be taken orally. The successful development and commercial introduction of such non-injection techniques could have a material adverse effect on our business, financial condition, results of operations and general prospects.

Competitors may succeed in developing competing technologies or obtaining governmental approval for products before we do. Competitors' products may gain market acceptance more rapidly than our products, or may be priced more favorably than our products. Developments by competitors may render our products, or potential products, noncompetitive or obsolete.

One of our competitors, Watson Pharmaceuticals, completed a Phase III study of its own oxybutynin gel for OAB in January 2008. While there is no guarantee their drug will ultimately be approved or launched in the U.S., at this point Watson's development of their oxybutynin gel is ahead of Anturol™ which may limit the success of Anturol™ in the market, if approved. Additionally, Watson has greater resources than we do, which may impact our ability to be competitive in the OAB market.

Although we have applied for, and have received, several patents, we may be unable to protect our intellectual property, which would negatively affect our ability to compete.

Our success depends, in part, on our ability to obtain and enforce patents for our products, processes and technologies and to preserve our trade secrets and other proprietary information. If we cannot do so, our competitors may exploit our innovations and deprive us of the ability to realize revenues and profits from our developments.

We currently hold approximately 87 patents and have an additional 80 applications pending in the U.S. and other countries. Our current patents may not be valid or enforceable and may not protect us against competitors that challenge our patents, obtain their own patents that may have an adverse effect on our ability to conduct business, or are able to otherwise circumvent our patents. Additionally, our technologies are complex and one patent may not be sufficient to protect our products where a series of patents may be needed. Further, we may not have the necessary financial resources to enforce or defend our patents or patent applications. In addition, any patent applications we may have made or may make relating to inventions for our actual or potential products, processes and technologies may not result in patents being issued or may result in patents that provide insufficient or incomplete coverage for our inventions.

To protect our trade secrets and proprietary technologies and processes, we rely, in part, on confidentiality agreements with employees, consultants and advisors. These agreements may not provide adequate protection for our trade secrets and other proprietary information in the event of any unauthorized use or disclosure, or if others lawfully and independently develop the same or similar information.

Others may bring infringement claims against us, which could be time-consuming and expensive to defend.

Third parties may claim that the manufacture, use or sale of our drug delivery technologies infringe their patent rights. If such claims are asserted, we may have to seek licenses, defend infringement actions or challenge the validity of those patents in the patent office or the courts. If we cannot avoid infringement or obtain required licenses on acceptable terms, we may not be able to continue to develop and commercialize our product candidates. Even if we were able to obtain rights to a third party's intellectual property, these rights may be non-exclusive, thereby giving our competitors potential access to the same intellectual property. If we are found liable for infringement or are not able to have these patents declared invalid, we may be liable for significant monetary damages, encounter significant delays in bringing products to market or be precluded from participating in the manufacture, use or sale of products or methods of drug delivery covered by patents of others. Even if we were able to prevail, any litigation could be costly and time-consuming and could divert the attention of our management and key personnel from our business operations. We may not have identified, or be able to identify in the future, United States or foreign patents that pose a risk of potential infringement claims. Furthermore, in the event a patent infringement suit is brought against us, the development, manufacture or potential sale of product candidates claimed to infringe on a third party's intellectual property may have to stop or be delayed. Ultimately, we may be unable to commercialize some of our product candidates as a result of patent infringement claims, which could harm our business.

We are aware of two related U.S. Patents issued to Watson Pharmaceuticals relating to a gel formulation of oxybutynin. We believe that we do not infringe these patents and that they should not have been granted. We may seek to invalidate these patents but there can be no assurance that we will prevail. If the patents are determined to be valid and if Anturol™ is approved, we may be delayed in our marketing of Anturol™ or incur significant expenses defending our patent position which may adversely affect the potential market value of Anturol™.

If the pharmaceutical companies to which we license our technologies lose their patent protection or face patent infringement claims for their drugs, we may not realize our revenue or profit plan.

The drugs to which our drug delivery technologies are applied are generally the property of the pharmaceutical companies. Those drugs may be the subject of patents or patent applications and other forms of protection owned by the pharmaceutical companies or third parties. If those patents or other forms of protection expire, become ineffective or are subject to the control of third parties, sales of the drugs by the collaborating pharmaceutical company may be restricted or may cease. Our expected revenues, in that event, may not materialize or may decline.

Our business may suffer if we lose certain key officers or employees or if we are not able to add additional key officers or employees necessary to reach our goals.

The success of our business is materially dependent upon the continued services of certain of our key officers and employees. The loss of such key personnel could have a material adverse effect on our

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business, operating results or financial condition. There can be no assurance that we will be successful in retaining key personnel. We consider our employee relations to be good; however, competition for personnel is intense and we cannot assume that we will continue to be able to attract and retain personnel of high caliber.

We are involved in international markets, and this subjects us to additional business risks.

We have offices and our pharmaceutical operations in Basel, Switzerland, and we also license and distribute our products in the European Community, Asia and the United States. These geographic localities provide economically and politically stable environments in which to operate. However, in the future, we intend to introduce products through partnerships in other countries. As we expand our geographic market, we will face additional ongoing complexity to our business and may encounter the following additional risks:

- increased complexity and costs of managing international operations;
- protectionist laws and business practices that favor local companies;
- dependence on local vendors;
- multiple, conflicting and changing governmental laws and regulations;
- difficulties in enforcing our legal rights;
- reduced or limited protections of intellectual property rights; and
- political and economic instability.

A significant portion of our international revenues is denominated in foreign currencies. An increase in the value of the U.S. dollar relative to these currencies may make our products more expensive and, thus, less competitive in foreign markets.

If we make any acquisitions, we will incur a variety of costs and might never successfully integrate the acquired product or business into ours.

We might attempt to acquire products or businesses that we believe are a strategic complement to our business model. We might encounter operating difficulties and expenditures relating to integrating an acquired product or business. These acquisitions might require significant management attention that would otherwise be available for ongoing development of our business. In addition, we might never realize the anticipated benefits of any acquisition. We might also make dilutive issuances of equity securities, incur debt or experience a decrease in cash available for our operations, or incur contingent liabilities and/or amortization expenses relating to goodwill and other intangible assets, in connection with future acquisitions.

If we do not have adequate insurance for product liability or clinical trail claims, then we may be subject to significant expenses relating to these claims.

Our business entails the risk of product liability and clinical trial claims. Although we have not experienced any material claims to date, any such claims could have a material adverse impact on our business. Insurance coverage is expensive and may be difficult to obtain, and may not be available in the future on acceptable terms, or at all. We maintain product and clinical trial liability insurance with coverage of $5 million per occurrence and an annual aggregate maximum of $5 million and evaluate our insurance requirements on an ongoing basis. If the coverage limits of the product liability insurance are not adequate, a claim brought against us, whether covered by insurance or not, could have a material adverse effect on our business, results of operations, financial condition and cash flows.

Risks Related to Regulatory Matters

We or our licensees may incur significant costs seeking approval for our products, which could delay the realization of revenue and, ultimately, decrease our revenues from such products.

The design, development, testing, manufacturing and marketing of pharmaceutical compounds, medical nutrition and diagnostic products and medical devices are subject to regulation by governmental authorities, including the FDA and comparable regulatory authorities in other countries. The approval process is generally lengthy, expensive and subject to unanticipated delays. Currently we, along with our partners, are actively pursuing marketing approval for a number of products from regulatory authorities in other countries and anticipate seeking regulatory approval from the FDA for products developed internally and pursuant to our license agreements. In the future we, or our partners, may need to seek approval for newly developed products. Our revenue and profit will depend, in part, on the successful introduction and marketing of some or all of such products by our partners or us.

Applicants for FDA approval often must submit extensive clinical data and supporting information to the FDA. Varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a drug product. Changes in FDA approval policy during the development period, or changes in regulatory review for each submitted new drug application also may cause delays or rejection of an approval. Even if the FDA approves a product, the approval may limit the uses or “indications” for which a product may be marketed, or may require further studies. The FDA also can withdraw product clearances and approvals for failure to comply with regulatory requirements or if unforeseen problems follow initial marketing.

We are currently developing Anturol™ for the treatment of overactive bladder (OAB). Anturol™ is the anticholinergic oxybutynin delivered by our proprietary ATD™ gel that is used to achieve therapeutic blood levels of the active compound that can be sustained over 24 hours after a single, daily application.

In February 2006, we announced the results of our Phase II dose ranging study for our ATD™ oxybutynin gel product Anturol™. The study was an open label, single period, randomized study using 48 healthy subjects and three different doses of Anturol™ over a 20 day period. Our overall conclusions of the study were positive. The FDA however, may not concur with our analysis of the data.

In July 2007, we completed a Special Protocol Assessment (SPA) with the FDA for a pivotal trial of Anturol. A SPA documents the FDA's agreement that the design and planned analysis of the trial adequately addresses objectives, in support of a regulatory submission such as a New Drug Application (NDA). The completion of the SPA does not ensure success of the trial or that the FDA will ultimately accept the results of the trial and we may never receive FDA approval for Anturol™ and without FDA approval, we cannot market or sell Anturol™.

In October 2007, we announced the first patient dosing in a pivotal safety and efficacy trial of Anturol™ for OAB. The three arm study will enroll approximately 600 patients for a 12-week clinical trial. The randomized, double-blind, placebo controlled, multi-center trial will principally evaluate the efficacy of Anturol™ when administered topically once daily for 12 weeks. The primary end point of the trial will be efficacy against the placebo defined as the reduction in the number of urinary incontinence episodes experienced. Secondary end points include changes from baseline in urinary urgency, average daily urinary frequency, patient perceptions as well as safety and tolerability. The initiation of the trial does not ensure success of the trial. We may not have the resources to complete the trial, Anturol™ may prove to not be efficacious, may not beat

placebo or may have undesired side effects not previously

experienced. We may have to modify the trial which may delay the trial or cause the costs of the trial to increase significantly. Additionally, the FDA may require further studies for approval. Any of these potential outcomes could have a negative impact on the value of our stock price.

We are also developing, with partners, injection devices for use with our partner's drugs. The regulatory path for approval of such combination products maybe subject to review by several centers within the FDA and although precedent and guidance exists for the requirements for such combination products, there is no assurance that the FDA will not change what it requires or how it reviews such submissions. Additionally, there is no assurance that the FDA will not require human clinical testing in order to commercialize these devices. Such changes in review processes or the requirement for clinical studies could delay anticipated launch dates or be at a cost which makes launching the device cost prohibitive for our partners. Such delay or failure to launch these devices could adversely affect our revenues and future profitability.

In July 2008, we announced that one of our device partners filed a Prior Approval supplemental new drug application (sNDA) for their product human growth hormone to add needle free injection to the product label. The sNDA submission included clinical and drug-device interaction studies performed over an extended period of time. The sNDA also references a 510(k) device filing previously submitted by us in 2006. The FDA required the supplemental filing since needle-free injection is a new route of administration for this product. The submission of the sNDA does not ensure that the FDA will accept or approve the filing and without FDA approval we cannot market or sell our needle free injector for the use with hGH in the U.S.

In other jurisdictions, we, and the pharmaceutical companies with whom we are developing technologies (both drugs and devices), must obtain required regulatory approvals from regulatory agencies and comply with extensive regulations regarding safety and quality. If approvals to market the products are delayed, if we fail to receive these approvals, or if we lose previously received approvals, our revenues may not materialize or may decline. We may not be able to obtain all necessary regulatory approvals. Additionally, clinical data that we generate or obtain from partners from FDA regulatory filings may not be sufficient for regulatory filings in other jurisdictions and we may be required to incur significant costs in obtaining those regulatory approvals.

The 505(b)(2) and 505(j) (ANDA) regulatory pathway for many of our potential products is uncertain and could result in unexpected costs and delays of approvals.

Transdermal and topical products indicated for the treatment of systemic or local treatments respectively are regulated by the FDA in the U.S. and other similar regulatory agencies in other countries as drug products. Transdermal and topical products are considered to be controlled release dosage forms and may not be marketed in the U.S. until they have been demonstrated to be safe and effective. The regulatory approval routes for transdermal and topical products include the filing of an NDA for new drugs, new indications of approved drugs or new dosage forms of approved drugs. Alternatively, these dosage forms can obtain marketing approval as a generic product by the filing of an ANDA, providing the new generic product is bioequivalent to and has the same labeling as a comparable approved product or as a filing under Section 505(b)(2) where there is an acceptable reference product. Other topical products for local treatment do not require the filing of either an NDA or ANDA, providing that these products comply with existing OTC monographs. The combination of the drug, its dosage form and label claims and FDA requirement will ultimately determine which regulatory approval route will be required.

Many of our transdermal product candidates may be developed via the 505(b)(2) route. The 505(b)(2) regulatory pathway is continually evolving and advice provided in the present is based on current standards, which may or may not be applicable when we potentially submit an NDA. Additionally, we must reference the most similar predicate products when submitting a 505(b)(2) application. It is therefore probable that:

- should a more appropriate reference product(s) be approved by the FDA at any time before or during the review of our NDA, we would be required to submit a new application referencing the more appropriate product;
- the FDA cannot disclose whether such predicate product(s) is under development or has been submitted at any time during another company's review cycle.

Drug delivery systems such as injectors are reviewed by the FDA and may be legally marketed as a medical device or may be evaluated as part of the drug approval process. Combination drug/device products raise unique scientific, technical and regulatory issues. The FDA has established an Office of Combination Products ("OCP") to address the challenges associated with the review and regulation of combination products. The OCP assists in determining strategies for the approval of drug/delivery combinations and assuring agreement within the FDA on review responsibilities. We may seek approval for a product including an injector and a generic pharmaceutical by filing an ANDA claiming bioequivalence and the same labeling as a comparable referenced product or as a filing under Section 505(b)(2) if there is an acceptable reference product. In reviewing the ANDA filing, the agency may decide that the unique nature of combination products allows them to dispute the claims of bioequivalence and/or same labeling resulting in our re-filing the application under Section 505(b)(2). If such combination products require filing under Section 505(b)(2) we may incur delays in product approval and may incur additional costs associated with testing including clinical trials. The result of an approval for a combination product under Section 505(b)(2) may result in additional selling expenses and a decrease in market acceptance due to the lack of substitutability by pharmacies or formularies.

Accordingly, these regulations and the FDA's interpretation of them might impair our ability to obtain product approval or effectively market our products.

Our business could be harmed if we fail to comply with regulatory requirements and, as a result, are subject to sanctions.

If we, or pharmaceutical companies with whom we are developing technologies, fail to comply with applicable regulatory requirements, the pharmaceutical companies, and we, may be subject to sanctions, including the following:

- warning letters;
- fines;
- product seizures or recalls;
- injunctions;
- refusals to permit products to be imported into or exported out of the applicable regulatory jurisdiction;
- total or partial suspension of production;
- withdrawals of previously approved marketing applications; or
- criminal prosecutions.

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Our revenues may be limited if the marketing claims asserted about our products are not approved.

Once a drug product is approved by the FDA, the Division of Drug Marketing, Advertising and Communication, the FDA's marketing surveillance department within the Center for Drugs, must approve marketing claims asserted by our pharmaceutical company partners. If we or a pharmaceutical company partner fails to obtain from the Division of Drug Marketing acceptable marketing claims for a product incorporating our drug technologies, our revenues from that product may be limited. Marketing claims are the basis for a product's labeling, advertising and promotion. The claims the pharmaceutical company partners are asserting about our drug delivery technologies, or the drug product itself, may not be approved by the Division of Drug Marketing.

Product liability claims related to participation in clinical trials or the use or misuse of our products could prove to be costly to defend and could harm our business reputation.

The testing, manufacturing and marketing of products utilizing our drug delivery technologies may expose us to potential product liability and other claims resulting from their use in practice or in clinical development. If any such claims against us are successful, we may be required to make significant compensation payments. Any indemnification that we have obtained, or may obtain, from contract research organizations or pharmaceutical companies conducting human clinical trials on our behalf may not protect us from product liability claims or from the costs of related litigation. Similarly, any indemnification we have obtained, or may obtain, from pharmaceutical companies with whom we are developing drug delivery technologies may not protect us from product liability claims from the consumers of those products or from the costs of related litigation. If we are subject to a product liability claim, our product liability insurance may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses that may have been suffered. A successful product liability claim against us, if not covered by, or if in excess of our product liability insurance, may require us to make significant compensation payments, which would be reflected as expenses on our statement of operations. Adverse claim experience for our products or licensed technologies or medical device, pharmaceutical or insurance industry trends may make it difficult for us to obtain product liability insurance or we may be forced to pay very high premiums, and there can be no assurance that insurance coverage will continue to be available on commercially reasonable terms or at all.

Risks Related to our Common Stock

Future conversions or exercises by holders of warrants or options could substantially dilute our common stock.

As of November 11, 2008, we have warrants outstanding that are exercisable, at prices ranging from $1.00 per share to $5.00 per share, for an aggregate of approximately 18,300,000 shares of our common stock. We also have options outstanding that are exercisable, at exercise prices ranging from $0.70 to $4.56 per share, for an aggregate of approximately 6,900,000 shares of our common stock. Purchasers of common stock could therefore experience substantial dilution of their investment upon exercise of the above warrants or options. The majority of the shares of common stock issuable upon exercise of the warrants or options held by these investors are currently registered.

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Sales of our common stock by our officers and directors may lower the market price of our common stock.

As of November 11, 2008, our officers and directors beneficially owned an aggregate of approximately 15,256,000 shares (or approximately 21%) of our common stock, including stock options exercisable within 60 days. If our officers and directors, or other stockholders, sell a substantial amount of our common stock, it could cause the market price of our common stock to decrease and could hamper our ability to raise capital through the sale of our equity securities.

We do not expect to pay dividends in the foreseeable future.

We intend to retain any earnings in the foreseeable future for our continued growth and, thus, do not expect to declare or pay any cash dividends in the foreseeable future.

Anti-takeover effects of certain certificate of incorporation and bylaw provisions could discourage, delay or prevent a change in control.

Our certificate of incorporation and bylaws could discourage, delay or prevent persons from acquiring or attempting to acquire us. Our certificates of incorporation authorizes our board of directors, without action of our stockholders, to designate and issue preferred stock in one or more series, with such rights, preferences and privileges as the board of directors shall determine. In addition, our bylaws grant our board of directors the authority to adopt, amend or repeal all or any of our bylaws, subject to the power of the stockholders to change or repeal the bylaws. In addition, our bylaws limit who may call meetings of our stockholders.

Item 6. Exhibits

(a) Exhibit Index

Exhibit No.	Description
10.1	Amendment to Senior Management Agreement with Robert F. Apple, dated November 12, 2008
10.2	Amendment to Employment Agreement with Peter Sadowski, Ph. D., dated November 12, 2008
10.3	Amendment to Employment Agreement with Dario Carrara, dated November 12, 2008
31.1	Section 302 CEO Certification
31.2	Section 302 CFO Certification
32.1	Section 906 CEO Certification
32.2	Section 906 CFO Certification

SIGNATURES

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

ANTARES PHARMA, INC.

November 13, 2008 /s/ Paul K. Wotton
Paul K. Wotton

President and Chief Executive Officer

November 13, 2008 /s/ Robert F. Apple
Robert F. Apple

Senior Vice President and Chief Financial Officer