

ANTARES PHARMA INC  
Form 10-Q  
November 13, 2007

**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, 2007

Commission File Number 1-32302

**ANTARES PHARMA, INC.**

A Delaware Corporation  
250 Phillips Blvd, Suite 290

IRS Employer Identification No. 41-1350192

Ewing, New Jersey 08618

(609) 359-3020

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large Accelerated filer  Accelerated filer  Non-accelerated filer

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

Yes  No

The number of shares outstanding of the Registrant's Common Stock, \$.01 par value, as of November 9, 2007, was 65,529,666.

ANTARES PHARMA, INC.

INDEX

		PAGE
PART I.	FINANCIAL INFORMATION	
Item 1.	Financial Statements	
	Consolidated Balance Sheets, as of September 30, 2007 (Unaudited) and December 31, 2006	3
	Consolidated Statements of Operations (Unaudited) for the three months and nine months ended 4 September 30, 2007 and 2006	4
	Consolidated Statements of Cash Flows (Unaudited) for the nine months ended September 30, 2007 and 2006	5
	Notes to Consolidated Financial Statements	6
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	13
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	18
Item 4.	Controls and Procedures	19
PART II.	OTHER INFORMATION	
Item 1A.	Risk Factors	21
Item 6.	Exhibits	35
	SIGNATURES	36

## PART I – FINANCIAL INFORMATION

## Item 1. FINANCIAL STATEMENTS

## ANTARES PHARMA, INC.

## CONSOLIDATED BALANCE SHEETS

	September 30, 2007 (Unaudited)	December 31, 2006
<b>Assets</b>		
Current Assets:		
Cash and cash equivalents	\$ 9,634,948	\$ 2,706,047
Short-term investments	15,708,873	4,953,421
Accounts receivable, less allowance for doubtful accounts of \$10,000	881,421	855,866
Other receivables	66,086	55,794
Inventories	117,178	84,779
Prepaid expenses and other current assets	504,255	221,669
Total current assets	26,912,761	8,877,576
Equipment, furniture and fixtures, net	428,443	382,096
Patent rights, net	848,508	813,592
Goodwill	1,095,355	1,095,355
Other assets	634,110	365,864
Total Assets	\$ 29,919,177	\$ 11,534,483
<b>Liabilities and Stockholders' Equity</b>		
Current Liabilities:		
Accounts payable	\$ 1,320,858	\$ 813,014
Accrued expenses and other liabilities	1,300,552	1,071,086
Notes payable and capital lease – current, net of discount of \$157,634	1,357,944	-
Deferred revenue	1,056,970	1,014,337
Total current liabilities	5,036,324	2,898,437
Notes payable and capital lease – long term, net of discount of \$137,103	3,334,093	-
Deferred revenue – long term	3,366,019	3,555,601
Total liabilities	11,736,436	6,454,038
Stockholders' Equity:		
Common Stock: \$0.01 par; authorized 100,000,000 shares; 65,529,666 and 53,319,622 issued and outstanding at September 30, 2007 and December 31, 2006, respectively	655,296	533,196

Edgar Filing: ANTARES PHARMA INC - Form 10-Q

Additional paid-in capital	125,003,062	106,792,974
Prepaid license discount	(2,158,743 )	(2,305,929 )
Accumulated deficit	(104,659,804 )	(99,322,453 )
Accumulated other comprehensive loss	(657,070 )	(617,343 )
	18,182,741	5,080,445
Total Liabilities and Stockholders' Equity	\$ 29,919,177	\$ 11,534,483

See accompanying notes to consolidated financial statements.

3

---

## ANTARES PHARMA, INC.

## CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

	For the Three Months Ended		For the Nine Months Ended	
	September 30,		September 30,	
	2007	2006	2007	2006
Revenue:				
Product sales	\$ 904,495	\$ 477,176	\$ 2,599,305	\$ 1,475,287
Development revenue	115,527	69,910	906,581	431,321
Licensing fees	104,210	170,616	2,098,291	246,898
Royalties	106,442	38,922	276,510	98,873
Total revenue	1,230,674	756,624	5,880,687	2,252,379
Cost of revenue:				
Cost of product sales	513,308	273,127	1,377,832	871,590
Cost of development revenue	38,332	46,571	209,091	200,821
Total cost of revenue	551,640	319,698	1,586,923	1,072,411
Gross profit	679,034	436,926	4,293,764	1,179,968
Operating expenses:				
Research and development	1,652,129	893,279	3,997,381	2,862,340
Sales, marketing and business development	369,625	278,805	1,185,959	987,114
General and administrative	1,346,657	1,260,173	4,462,346	4,219,862
	3,368,411	2,432,257	9,645,686	8,069,316
Operating loss	(2,689,377 )	(1,995,331 )	(5,351,922 )	(6,889,348 )
Other income (expense):				
Interest income	310,285	103,698	574,803	257,117
Interest expense	(228,997 )	(36 )	(539,835 )	(1,766 )
Foreign exchange losses	(9,605 )	(9,700 )	(38,452 )	(9,958 )
Other, net	6,962	(23,498 )	18,055	(42,171 )
	78,645	70,464	14,571	203,222
Net loss	(2,610,732 )	(1,924,867 )	(5,337,351 )	(6,686,126 )
Deemed dividend to warrant holders				(99,500 )
Net loss applicable to common shares	\$ (2,610,732 )	\$ (1,924,867 )	\$ (5,337,351 )	\$ (6,785,626 )
Basic and diluted net loss per common share	\$ (0.04 )	\$ (0.04 )	\$ (0.09 )	\$ (0.13 )
Basic and diluted weighted average common shares outstanding	64,660,101	53,094,622	57,607,935	51,032,017

See accompanying notes to consolidated financial statements.

4

---

## ANTARES PHARMA, INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	For the Nine Months Ended September 30,	
	2007	2006
Cash flows from operating activities:		
Net loss	\$ (5,337,351 )	\$ (6,686,126 )
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	185,956	230,027
Stock-based compensation expense	930,377	728,089
Amortization of prepaid license discount	147,186	147,186
Amortization of debt discount and issuance costs	153,297	-
Changes in operating assets and liabilities:		
Accounts receivable	(12,969 )	(9,211 )
Other receivables	(105,434 )	(142,469 )
Inventories	(32,399 )	(52,316 )
Prepaid expenses and other current assets	(201,538 )	(30,507 )
Other assets	(200,520 )	(20,401 )
Accounts payable	505,094	(202,092 )
Accrued expenses and other current liabilities	161,892	18,370
Deferred revenue	(191,304 )	396,712
Net cash used in operating activities	(3,997,713 )	(5,622,738 )
Cash flows from investing activities:		
Purchases of short-term investments	(18,929,240 )	(8,743,848 )
Proceeds from maturity of short-term investments	8,275,674	2,939,036
Additions to patent rights	(104,690 )	(83,033 )
Purchases of equipment, furniture and fixtures	(27,684 )	(28,161 )
Net cash used in investing activities	(10,785,940 )	(5,916,006 )
Cash flows from financing activities:		
Proceeds from issuance of common stock, net	14,742,671	9,782,055
Proceeds from exercise of warrants and stock options	2,292,692	1,110,086
Proceeds from notes payable	5,000,000	-
Principal payments on long-term debt	(131,956 )	-
Capitalized debt issuance costs	(181,125 )	-
Net cash provided by financing activities	21,722,282	10,892,141
Effect of exchange rate changes on cash and cash equivalents	(9,728 )	1,611
Net increase (decrease) in cash and cash equivalents	6,928,901	(644,992 )
Cash and cash equivalents:		
Beginning of period	2,706,047	2,718,472
End of period	\$ 9,634,948	\$ 2,073,480

See accompanying notes to consolidated financial statements

5

---



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 primary delivery platforms (1) transdermal gels, (2) fast-melt tablets, and (3) injection devices. The corporate headquarters are located in Ewing, New Jersey, with research and production facilities for the injection devices in Minneapolis, Minnesota, and research, development and commercialization facilities for the transdermal gels and fast-melt tablets in Basel, Switzerland.

**2. Basis of Presentation**

The accompanying unaudited 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 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 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, 2006. Operating results for the three and nine-month periods ended September 30, 2007, are not necessarily indicative of the results that may be expected for the year ending December 31, 2007.

*Short-Term Investments*

All short-term investments are commercial paper or U.S. government agency discount notes that mature within one year of purchase and are classified as held-to-maturity because the Company has the positive intent and ability to hold the securities to maturity. The securities are carried at their amortized cost. At September 30, 2007 and December 31, 2006 the securities had a fair value of \$15,730,516 and \$4,951,654, respectively, and a carrying value of \$15,708,873 and \$4,953,421, respectively.

*Reclassifications*

The Company reclassified expenses for quality and regulatory activities previously reported as general and administrative expenses to research and development expenses. The amounts of the reclassifications were \$60,782 and \$209,390 for the three and nine month periods ended September 30, 2006, respectively. This reclassification did not impact previously reported operating loss, net loss or net loss per share.

**3. Notes Payable and Capital Lease**

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. A second tranche of \$5,000,000 is available after September 30, 2007 but before December 31, 2007 upon meeting certain conditions. The per annum interest rate is equal to the sum of the yield for three-

6

---

## Edgar Filing: ANTARES PHARMA INC - Form 10-Q

year U.S. treasury bills as quoted by Bloomberg, plus 800 basis points calculated (i) in the case of the first tranche, on the business day prior to the first funding date and (ii) in the case of the second tranche, on the business day prior to the second funding date (as such term is defined in the Credit Agreement). In addition, once set, the applicable interest rate for each tranche will be fixed for the applicable term. The stated interest rate for the first tranche is 12.7%. 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 Company has pledged certain property as collateral, including all intellectual property.

The credit agreement contains certain covenants and provisions that affect the Company, including, without limitation, covenants and provisions that:

- restrict its ability to create or incur indebtedness (subject to enumerated exceptions);
- restrict its ability to create or incur certain liens on its property (subject to enumerated exceptions);
- in certain circumstances, require it to maintain, on a consolidated basis, unrestricted cash and cash equivalents of at least \$2,500,000;
- in certain circumstances, restrict its 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;
- restrict its ability to make certain investments.

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, of which 400,000 vested upon closing of the first tranche and of which 240,000 will vest on the occurrence of the drawdown of the second tranche. The fair value of the vested warrants related to the first tranche was \$400,276, calculated using the Black-Scholes valuation model, and was recorded as debt discount and is being amortized and recorded as interest expense using the interest method over the forty-two month term.

The Company capitalized debt issuance costs totaling \$181,125, which is being amortized and recorded as interest expense using the interest method over the forty-two month term.

Total interest expense related to the credit facility in the first nine months of 2007 was \$527,191. Cash paid for interest in the first nine months was \$372,156.

Principal payments of \$1,476,549, \$1,675,381 and \$1,733,239 are due in each of the twelve month periods ended September 30, 2008, 2009 and 2010, respectively.

In the second quarter of 2007 the Company acquired lab equipment under a three year capital lease. The equipment and capital lease obligation were recorded at a value of approximately \$115,000. Principal payments of approximately \$39,000, \$41,000 and \$21,000 are due in each of the twelve month periods ended September 30, 2008, 2009, and 2010.



#### 4. Stock Based Compensation

The Company accounts for employee stock compensation cost using the fair value method pursuant to SFAS No. 123R, 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 adopted SFAS No. 123R in the first quarter of 2006 using the modified prospective transition method.

The Company's stock option and equity incentive plans allow for the grants of options, restricted stock and/or performance awards to officers, directors, consultants and employees. Under the Company's 2006 Equity Incentive Plan, the maximum number of shares of stock that may be granted to any one participant during a calendar year is 500,000 shares, and no more than 500,000 shares may be issued as restricted stock grants, restricted stock units and performance awards. 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, 2007, these plans had 2,412,610 shares available for grant. Stock option exercises are satisfied through the issuance of new shares.

A summary of stock option activity under the plans as of September 30, 2007 and the changes during the nine-month period then ended is as follows:

		<b>Weighted</b>	<b>Weighted</b>	
	<b>Number of</b>	<b>Average</b>	<b>Average</b>	<b>Aggregate</b>
	<b>Shares</b>	<b>Exercise</b>	<b>Remaining</b>	<b>Intrinsic</b>
		<b>Price (\$)</b>	<b>Contractual</b>	<b>Value (\$)</b>
			<b>Term (Years)</b>	
Outstanding at December 31, 2006	4,426,759	1.65		
Granted	1,307,632	1.42		
Exercised	(35,000 )	1.54		
Forfeited	(106,000 )	2.26		
Outstanding at September 30, 2007	5,593,391	1.58	7.2	636,858
Exercisable at September 30, 2007	3,930,695	1.67	6.5	435,486

Total recognized compensation expense for stock options was approximately \$823,000 and \$583,000 for the first nine months of 2007 and 2006, respectively. As of September 30, 2007, there was approximately \$1,763,000 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 2007 and 2006 were estimated as \$1.14 and \$1.37, respectively, on the date of grant using the Black-Scholes option pricing model based on the assumptions noted in the table below. Expected volatilities are based on the historical volatility of the Company's stock. The weighted average expected life is based on both historical and anticipated employee behavior.



	September 30,			
	2007		2006	
Risk-free interest rate	4.7	%	4.4	%
Annualized volatility	109.0	%	127.0	%
Weighted average expected life, in years	5.0		7.0	
Expected dividend yield	0.0	%	0.0	%

The employment agreements with the Chief Executive Officer, Chief Financial Officer and other members of executive management include stock-based incentives under which the executives could be awarded up to 1,365,000 restricted shares of common stock upon the occurrence of various triggering events and authorization by stockholders, in certain circumstances, of additional shares under existing or future plans. Approximately 1,033,000 of these shares relate to performance criteria that were not yet considered probable of achievement. Expense of approximately \$71,000 was recognized in the first nine months of 2007 in connection with potential performance based awards totaling approximately 68,000 shares of common stock for the Chief Financial Officer, of which 22,727 shares were issued in the second quarter of 2007. The Chief Executive Officer was awarded 86,666 shares of common stock in 2006 upon a triggering event being attained. A total of approximately \$61,000 in compensation expense was recorded in 2006 and 2005 in connection with these shares. The weighted average grant date fair value of the remaining awards considered probable of achievement by the Chief Executive Officer was \$0.40 per share, which resulted in a total fair value of \$80,000, of which approximately \$23,000 was recognized in the first nine months of 2007.

## 5. Stockholders' Equity

### *Common Stock, Options and Warrants*

In July of 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.

In March of 2006, the Company received proceeds of \$9,782,055, net of offering costs of \$1,180,445, in a private placement of its common stock in which a total of 8,770,000 shares of common stock were sold at a price of \$1.25 per share. In connection with the private placement, the Company issued five-year warrants to purchase an aggregate of 7,454,500 shares of common stock with an exercise price of \$1.50 per share.

Warrant and stock option exercises during the first nine months of 2007 and 2006 resulted in proceeds of \$2,292,692 and \$1,110,086, respectively, and in the issuance of 2,187,317 and 1,292,020 shares of common stock, respectively.

During the first nine months of 2007 and 2006, the Company granted options to purchase a total of 1,307,632 and 1,455,000 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 \$1.23 to \$1.65 per share in 2007 and at exercise prices ranging from \$1.43 to \$1.55 in 2006. 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.





## Edgar Filing: ANTARES PHARMA INC - Form 10-Q

Warrants to purchase a total of 23,141,021 shares of common stock were outstanding at September 30, 2007. The weighted average exercise price of the warrants was \$1.49.

### *Deemed Dividend to Warrant Holders*

In 2006, in connection with the exercise of 210,000 warrants, the Company agreed to issue new three-year warrants for the purchase of 105,000 shares of common stock with an exercise price of \$1.35. The new warrants were issued in the first quarter of 2006 and were estimated to have a fair value of \$99,500 using the Black-Scholes option pricing model. The fair value of the new warrants was recorded as a return to the warrant holders and increased the net loss applicable to common stockholders in computing net loss per share.

### **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.

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
Net loss applicable to common shares	\$ (2,610,732 )	\$ (1,924,867 )	\$ (5,337,351 )	\$ (6,785,626 )
Basic and diluted weighted avg common shares outstanding	64,660,101	53,094,622	57,607,935	51,032,017
Basic and diluted net loss per common share	\$ (0.04 )	\$ (0.04 )	\$ (0.09 )	\$ (0.13 )

Potentially dilutive stock options and warrants excluded from dilutive loss per share because their effect was anti-dilutive totaled 28,734,412 and 26,029,542 at September 30, 2007 and 2006, respectively.

The weighted average exercise price of the stock options and warrants outstanding at September 30, 2007 and 2006 was \$1.50 and \$1.41, respectively.

### **7. Industry Segment and Operations by Geographic Areas**

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

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

10

---

Edgar Filing: ANTARES PHARMA INC - Form 10-Q

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

	<b>September 30,</b>	<b>December 31,</b>
	<b>2007</b>	<b>2006</b>
Switzerland	\$ 1,677,897	\$ 1,655,869
United States of America	28,241,280	9,878,614
	<b>\$ 29,919,177</b>	<b>\$ 11,534,483</b>

Revenues by customer location are summarized as follows:

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
United States of America	\$ 187,103	\$ 196,750	\$ 2,436,718	\$ 657,361
Europe	987,672	467,740	3,160,216	1,296,231
Other	55,899	92,134	283,753	298,787
	<b>\$ 1,230,674</b>	<b>\$ 756,624</b>	<b>\$ 5,880,687</b>	<b>\$ 2,252,379</b>

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

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
Ferring	\$910,688	\$ 323,872	\$ 2,419,103	\$ 1,119,047
BioSante Pharmaceuticals, Inc.	69,277	41,761	1,907,339	85,229
Undisclosed	86,953	-	626,236	-
Jazz Pharmaceuticals	27,102	18,228	224,864	302,293
Undisclosed	-	124,601	-	124,601

**8. Comprehensive Loss**

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
Net loss	\$ (2,610,732 )	\$ (1,924,867 )	\$ (5,337,351 )	\$ (6,686,126 )
Change in cumulative translation adjustment	(30,894 )	5,779	(39,727 )	(9,288 )
Comprehensive loss	<b>\$ (2,641,626 )</b>	<b>\$ (1,919,088 )</b>	<b>\$ (5,377,078 )</b>	<b>\$ (6,695,414 )</b>

**9. New Accounting Pronouncements**

The Company adopted the provisions of FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109" on January 1, 2007. This interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, "Accounting for Income Taxes." This interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. It also provides guidance on derecognition, classification,

interest and penalties, accounting in interim periods, disclosure and transition. The adoption of this accounting pronouncement did not have a material impact on the Company's consolidated financial statements.

In September 2006, the FASB issued Statement of Financial Accounting Standards ("SFAS") No. 157, "Fair Value Measurements" which is effective for fiscal years beginning after November 15, 2007 and for interim periods within those years. This statement defines fair value, establishes a framework for measuring fair value and expands the related disclosure requirements. The Company believes this accounting pronouncement will not have a material impact on its consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities—Including an amendment of FASB Statement No. 115." SFAS No. 159 permits entities to choose to measure many financial instruments and certain warranty and insurance contracts at fair value on a contract-by-contract basis. A business entity is required to report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. SFAS No. 159 includes financial statement presentation and disclosure requirements for assets and liabilities reported at fair value as a consequence of the election. The objective of this Statement is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. The provisions of SFAS No. 159 are effective for the Company beginning January 1, 2008. The Company is currently evaluating the impact of adopting this pronouncement on its consolidated financial statements and related disclosures.

#### **10. License Agreements**

In September 2007, the Company entered into a worldwide product development and license agreement with an undisclosed company for a product that will utilize the Company's oral disintegrating tablet delivery technology. Under the agreement, an upfront payment, development milestones, and royalties on product sales are to be received by the Company under certain circumstances.

In July 2007, the Company entered into a worldwide product development and license agreement with Jazz Pharmaceuticals for a product that will utilize the Company's transdermal gel delivery technology. Under the agreement, an upfront payment, development milestones, and royalties on product sales are to be received by the Company under certain circumstances.

The upfront payments due under these two agreements totaled approximately \$625,000, nearly all of which has been deferred and will be recognized over the development periods.

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

**Overview**

The Company develops, produces and markets pharmaceutical delivery products, including transdermal gels, oral fast-melting tablets and reusable needle-free and disposable mini-needle injector systems. In addition, the Company has several products and compound formulations under development. The Company has operating facilities in the U.S. and Switzerland. The U.S. operation develops reusable needle-free and disposable mini-needle injector systems and manufactures and markets reusable needle-free injection devices and related disposables. These operations, including all manufacturing and some U.S. administrative activities, are located in Minneapolis, Minnesota. The Company also has operations located in Basel, Switzerland, which consists of administration and facilities for the development of transdermal gels and oral fast-melt 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 its primary customers. The Company has negotiated and executed licensing relationships in the growth hormone segment (reusable needle-free devices in Europe and Asia) and the transdermal gels and oral fast-melt tablet segments (several license and development programs are in place worldwide, including the United States and Europe). 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, has granted a development license to its reusable needle-free technology in the diabetes and obesity fields to Eli Lilly and Company on a worldwide basis, and has licensed both disposable and reusable injection devices to Teva Pharmaceuticals for use in undisclosed fields and territories.

The Company is reporting a net loss of \$5,337,351 for the nine-month period ended September 30, 2007 and expects to report a net loss for the year ending December 31, 2007, as marketing and 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, 2006. The Company has made no changes to these policies during 2007.

### *Three and Nine Months Ended September 30, 2007 and 2006*

#### *Revenues*

Total revenues for the three and nine months ended September 30, 2007 were \$1,230,674 and \$5,880,687, respectively, compared to revenues for the same prior-year periods of \$756,624 and \$2,252,379. The increase in revenues in the three month period was primarily due to increases in product sales and royalties. The nine month period resulted in increases in all revenue categories, with the most significant increase recognized in licensing fees as a result of \$1,750,000 received under a sublicense arrangement related to an existing license agreement with BioSante Pharmaceuticals, Inc. Product sales were higher in each period mainly due to increased revenue from the Company's major European customer, Ferring. The increase in revenue from Ferring was due to increases in the number of needle-free injector devices and disposable components sold and a renegotiated contract with Ferring in which selling prices were increased. The increase in development revenue resulted primarily from agreements related to use of the Company's proprietary ATD™ gel technology and oral fast-melting tablet technology. The royalty revenue increases were directly related to the increase in the number of injector devices sold to Ferring, as well as a renegotiated increased royalty rate with Ferring.

#### *Cost of Revenues*

The cost of product sales are related to injection devices and related products. For the three and nine month periods ended September 30, 2007, cost of product sales were \$513,308 and \$1,377,832, respectively, compared to \$273,127 and \$871,590 for the same periods of the prior year. The cost of product sales increases were directly related to the increases in product sales. Cost of product sales as a percentage of product sales decreased in the nine month period to 53% in 2007 from 59% in 2006, and was unchanged at 57% for the three months ended September 30, 2007 and 2006. The decrease in the nine-month period was due primarily to a higher sales volume absorbing a similar level of fixed overhead costs along with increases in selling prices.



## Edgar Filing: ANTARES PHARMA INC - Form 10-Q

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 thru to the customer at little or no markup, resulting in very low margins. Cost of development revenue as a percentage of

14

---

## Edgar Filing: ANTARES PHARMA INC - Form 10-Q

development revenue was 33% and 67% for the third quarter of 2007 and 2006, respectively and was 23% and 47% for the nine-month periods ended September 30, 2007 and 2006, respectively.

### *Research and Development*

Research and development expenses were \$1,652,129 and \$3,997,381 in the three and nine-month periods ended September 30, 2007, respectively, compared to \$893,279 and \$2,862,340 in the same periods of the prior year. The increases in the third quarter and first nine months of 2007 compared to the same periods of 2006 were due primarily to costs incurred in connection with activities such as contract research organization (CRO) initiation, site recruitment, drug supply and database initiation in anticipation of starting a Phase III study of Anturo1™ (oxybutynin gel) for the treatment of overactive bladder in the fourth quarter of 2007.

### *Sales, Marketing and Business Development*

Sales, marketing and business development expenses totaled \$369,625 and \$1,185,959 for the three and nine-month periods ended September 30, 2007, respectively, compared to \$278,805 and \$987,114 in the same prior year periods. The increase in the three-month period was primarily due to increases in payroll, legal fees and professional services. The increase in the nine-month period was primarily due to increases in payroll and legal fees. The payroll increases were partially due to additional personnel and the legal fees increases were due to increased activity as a result of new licenses/agreements being completed or in progress.

### *General and Administrative*

General and administrative expenses totaled \$1,346,657 and \$4,462,346 in the three and nine-month periods ended September 30, 2007, respectively, compared to \$1,260,173 and \$4,219,862 in the same periods of the prior year. The increases in each period were due mainly to increases in travel, stock based compensation and patent related expenses. These increases were partially offset by decreases in various professional service expenses.

### *Other Income (Expense)*

Other income was \$78,645 and \$14,571 in the three and nine-month periods ended September 30, 2007, respectively, compared to income of \$70,464 and \$203,222 in the same periods of the prior year. The increase in the three-month period was due primarily to an increase in interest income partially offset by an increase in interest expense. The decrease in the nine-month period was due primarily to an increase in interest expense partially offset by an increase in interest income. Interest income increased in each period due to higher cash and investment balances resulting from the debt and equity financings in the first and third quarters of 2007, respectively. Interest expense increased due to the \$5,000,000 borrowed under a credit agreement in the first quarter of 2007.

**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 operate primarily by raising capital and incurring debt.

15

---

## Edgar Filing: ANTARES PHARMA INC - Form 10-Q

In July of 2007 the Company received proceeds of \$14,742,670, net of offering costs of \$1,257,330, 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. The Company intends to use net proceeds from the financing for the Phase III clinical study of Anturo1™, continuing the advancement of new products in the pipeline and for working capital and general corporate purposes.

In the first nine months of 2007 the Company received proceeds of \$2,292,692 from the exercise of warrants and stock options which resulted in the issuance of 2,187,317 shares of common stock.

In the second quarter of 2007 the Company acquired equipment under a three year capital lease. The equipment and capital lease obligation were recorded at a value of approximately \$115,000. Principal payments of approximately \$39,000, \$41,000 and \$21,000 are due in each of the twelve month periods ended September 30, 2008, 2009, and 2010.

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 additional working capital needs. A second tranche of \$5,000,000 is available after September 30, 2007 but before December 31, 2007 upon meeting certain conditions. The per annum interest rate is equal to the sum of the yield for three-year US treasury bills as quoted by Bloomberg, plus 800 basis points calculated (i) in the case of the first tranche, on the business day prior to the first funding date and (ii) in the case of the second tranche, on the business day prior to the second funding date (as such term is defined in the Credit Agreement). In addition, once set, the applicable interest rate for each tranche will be fixed for the applicable term. The stated interest rate for the first tranche is 12.7%. 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 contains certain covenants and provisions that affect the Company, including, without limitation, covenants and provisions that:

- restrict its ability to create or incur indebtedness (subject to enumerated exceptions);
- restrict its ability to create or incur certain liens on its property (subject to enumerated exceptions);
- in certain circumstances, require it to maintain, on a consolidated basis, unrestricted cash and cash equivalents of at least \$2,500,000;
- in certain circumstances, restrict its 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;
- restrict its ability to make certain investments.

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, of which 400,000 vested upon closing of the first tranche and of which 240,000 will vest on the occurrence of the drawdown of the second tranche.

In March of 2006 the Company received net proceeds of \$9,782,055 in a private placement of its common stock in which a total of 8,770,000 shares of common stock were sold at a price of \$1.25 per share. In connection with the private placement, the Company issued five-year warrants to purchase an aggregate of 7,454,500 shares of common stock with an exercise price of \$1.50 per share. In the first half of 2006 the Company also received proceeds of \$1,110,086 in connection with warrant and stock option exercises which resulted in the issuance of 1,292,020 shares of common stock.



The Company believes that the combination of the recent equity and debt financings and projected product sales, product development, license revenues, milestone payments and royalties will provide sufficient funds to support operations beyond 2008. During 2007, the Company believes capital expenditures may increase to approximately \$1,000,000 primarily in connection with tooling and production equipment related to the commercial launch of certain devices associated with injection device deals. If the Company does need 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 drug technologies, 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 \$3,997,713 and \$5,622,738 for the nine-month periods ended September 30, 2007 and 2006, respectively. The difference between 2007 and 2006 was mainly the result of a decrease in the amount of the net loss and an increase in noncash expenses. The net loss reduction in the first nine months of 2007 was primarily due to \$1,750,000 received under a sublicense arrangement related to an existing license agreement with BioSante Pharmaceuticals, Inc.

Noncash expenses in the first nine months of 2007 totaled \$1,416,816 compared to \$1,105,302 in 2006. The increase was due primarily to the amortization of debt discount and issuance costs related to the \$5,000,000 credit facility and an increase in stock-based compensation expense.

#### *Investing Activities*

Net cash used in investing activities was \$10,785,940 and \$5,916,006 for the nine-month periods ended September 30, 2007 and 2006, respectively. This was primarily due to purchases of short-term investments of \$18,929,240 and \$8,743,848 in 2007 and 2006, respectively. The purchases were partially offset by proceeds from the maturity of short-term investments of \$8,275,674 and \$2,939,036 in 2007 and 2006, respectively. The increase in short-term investment purchases in 2007 was the result of an increase in available cash from the debt and equity financings in the first and third quarters of 2007, respectively.

#### *Financing Activities*

Net cash provided by financing activities totaled \$21,722,282 in the first nine-months of 2007, which consisted primarily of proceeds from the issuance of common stock related to the private placement of \$14,742,671, proceeds from the note payable of \$5,000,000 and proceeds from the exercise of warrants and stock options of \$2,292,692. Net cash provided by financing activities in the first nine-months of 2006 was \$10,892,141, which consisted of net proceeds from the sale of common stock of \$9,782,055 and proceeds from the exercise of warrants and stock options of \$1,110,086.

### *New Accounting Pronouncements*

The Company adopted the provisions of FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109" on January 1, 2007. This interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, "Accounting for Income Taxes." This interpretation

prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. It also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The adoption of this accounting pronouncement did not have a material impact on the Company's consolidated financial statements.

In September 2006, the FASB issued Statement of Financial Accounting Standards ("SFAS") No. 157, "Fair Value Measurements" which is effective for fiscal years beginning after November 15, 2007 and for interim periods within those years. This statement defines fair value, establishes a framework for measuring fair value and expands the related disclosure requirements. The Company believes this accounting pronouncement will not have a material impact on its consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities—Including an amendment of FASB Statement No. 115." SFAS No. 159 permits entities to choose to measure many financial instruments and certain warranty and insurance contracts at fair value on a contract-by-contract basis. A business entity is required to report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. SFAS No. 159 includes financial statement presentation and disclosure requirements for assets and liabilities reported at fair value as a consequence of the election. The objective of this Statement is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. The provisions of SFAS No. 159 are effective for the Company beginning January 1, 2008. The Company is currently evaluating the impact of adopting this pronouncement on its consolidated financial statements and related disclosures.

*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 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 the Company's financial results for the three and nine-month periods ended September 30, 2007 and 2006 was not material.

Typically, the Company's short-term investments are commercial paper or U.S. government agency discount notes that mature within one year 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



18

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.

*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 person 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 Quarterly Report on Form 10-Q are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. When used in this Quarterly Report on Form 10-Q, the words "may," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "intends," "potential" or "continue" and similar expressions are generally intended to identify forward-looking statements. Because these

## Edgar Filing: ANTARES PHARMA INC - Form 10-Q

forward-looking statements involve risks and uncertainties, including those described in Item 1A of this Quarterly 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.

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 part or all of your investment. In this Section, the terms "we" and "our" 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 (\$5,337,351) for the nine months ended September 30, 2007 and net losses of (\$8,099,846) and (\$8,497,956) in the fiscal years ended 2006 and 2005, respectively. In addition, we have accumulated aggregate net losses from the inception of business through September 30, 2007 of (\$104,659,804). 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. A second tranche of \$5,000,000 is available after September 30, 2007 but before December 31, 2007 under certain conditions. 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 beyond 2008. However, 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 drug technologies, 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:

## Edgar Filing: ANTARES PHARMA INC - Form 10-Q

- 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;
- the level of product competition and of price competition;

21

---

- 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.

*As we 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, fast-melt tablet, disposable mini-needle 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 and in regulatory matters and bringing such products to market; therefore, we may experience difficulties in making this change or not be able to achieve the change at all.

*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 2007 we derived approximately 41%, 32% and 11% of our revenue from Ferring, BioSante Pharmaceuticals and an undisclosed company, respectively, and in 2006, we derived approximately 50% and 13% of our revenue from Ferring and Jazz Pharmaceuticals, respectively.

The loss of any of these customers or partners 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 three License, Development and/or Supply agreements since November of 2005 with Teva Pharmaceutical Industries Ltd. or an affiliate of Teva. Although certain upfront payments have been received, there have been no commercial sales and there can be no assurance that there ever will be commercial sales 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.

In September 2007, we entered into a worldwide product development and license agreement with an undisclosed company. 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.

*If we or our third-party manufacturer are unable to supply Ferring with our devices pursuant to our current license agreement with Ferring, Ferring would 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 manufacturing margins from Ferring.

*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, resources or facilities to manufacture Anturo1™, which is currently in development for overactive bladder, or any other of our future drug candidates. We must contract with manufacturers to produce Anturo1™ 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 not contracted with a commercial supplier of active pharmaceutical ingredients of oxybutynin for Anturo1™ at this time. We are currently working towards selecting a manufacturer to provide us with oxybutynin in a manner which meets FDA requirements.

We have contracted with Patheon, a manufacturing development company, to supply clinical quantities of Anturo1™ in a manner that meets FDA requirements. The FDA has not approved the manufacturing processes of Patheon for Anturo1. Any failure by Patheon to achieve compliance with FDA standards could significantly harm our business since we do not currently have an approved secondary manufacturer for Anturo1™.

*We have limited commercial device manufacturing experience and may experience difficulties related to the use of new device materials and procedures, which could increase our production costs and, ultimately, decrease our profits*



## Edgar Filing: ANTARES PHARMA INC - Form 10-Q

Our past assembly, testing and device manufacturing experience for our needle-free device has involved the assembly of products from machined stainless steel and composite components in limited

23

---

quantities. Our planned future device business necessitates significant changes and additions to our contract manufacturing and assembly process. 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 entered into a manufacturing agreement under which a third party assembles our MJ7 devices and certain related disposable component parts. There can be no assurance that this third-party manufacturer 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 also continue to outsource manufacturing of our 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 manufacturer's business such as their potential inability to perform from a technical, operational or financial standpoint. We have not entered into any manufacturing agreement for these products.

*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 needle-free and mini-needle injectors, transdermal gels, fast-melt 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.

## Edgar Filing: ANTARES PHARMA INC - Form 10-Q

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

24

---

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.

*A 2002 National Institute of Health (“NIH”) study and the 2003 findings from the Million Women Study first launched in 1997 in the U.K. 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 yet assess the impact any of the studies’ results may have on our contracts or on our partners’ perspective of the market for transdermal gel products designed for HRT. We also 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 newly approved product.

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

Because transdermal gels are a newer, less understood method of drug delivery, our potential partners and consumers 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.

We are developing Anturol, our oxybutynin gel for overactive bladder. We may seek a pharmaceutical partner to assist in the payment for the development and marketing of this potential product. 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.

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 services, 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 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.

Edgar Filing: ANTARES PHARMA INC - Form 10-Q

Elestrin®, for which we will receive royalties from our partner based on any commercial sales, was launched in June 2007. Therefore, we have no way of knowing at this time if health insurance companies

26

---

will reimburse patients for the use of Elestrin® as this typically becomes known in the latter part of the first year of launch.

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

One of our 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.

*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.



*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 and needle-free 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 fast-melt 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. Drug delivery companies that compete with our technologies include Bioject Medical Technologies, Inc., Bentley Pharmaceuticals, Inc., Auxillium, BioChemics, Inc., Aradigm, Cellegy Pharmaceuticals, Inc., Watson Pharmaceuticals, Cardinal Health, CIMA Laboratories, Laboratoires Besins-Iscovesco, MacroChem Corporation, NexMed, Inc., The Medical House and Novavax, Inc., 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.

*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 70 patents and have an additional 98 applications pending in the U.S. and other countries. In early 2007 the U.S. patent office issued two patents in our ATD™ gel platform including a patent related to our formulation of Elestrin®, an estradiol gel product approved by the FDA for hormone replacement therapy and a patent related to our core gel technology. The patents



have expiration dates ranging from 2015 to 2022. In addition to issued patents and patent applications, we also have trade secrets in all of our technology platforms.

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. 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. Further, we may not have the necessary financial resources to enforce or defend our patents or patent applications.

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 court. If we cannot obtain required licenses, or obtain 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 a U.S. Patent issued to Watson Pharmaceuticals relating to a gel formulation of oxybutynin. We believe that we do not infringe this patent and that it should not have been issued. We may seek to invalidate this patent but there can be no assurance that we will prevail. If the patent is determined to be valid and if Anturo1™ is approved, we may be delayed in our marketing and the potential market value of Anturo1™ may be affected.

*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 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 a research facility 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*

## Edgar Filing: ANTARES PHARMA INC - Form 10-Q

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.

30

---

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

Our business entails the risk of product liability claims. Although we have not experienced any material product liability claims to date, any such claims could have a material adverse impact on our business. We maintain product liability insurance with coverage of \$5 million per occurrence and an annual aggregate maximum of \$5 million. We evaluate our insurance requirements on an ongoing basis.

### **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 evaluating Anturool™ for the treatment of overactive bladder (OAB). Anturool™ 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 Anturool™. The study was an open label, single period, randomized study using 48 healthy subjects and three different doses of Anturool™ 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 Anturool. 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

## Edgar Filing: ANTARES PHARMA INC - Form 10-Q

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 AnturoI™ and without FDA approval, we cannot market or sell AnturoI™.



In August 2007, we initiated a pivotal safety and efficacy trial of AnturoI™ 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 AnturoI™ 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, AnturoI™ may prove to not be efficacious, may not beat placebo or may have undesired side effects not previously experienced. 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.

Additionally, we are developing, with partners, injection devices for use with our partner's drugs. The regulatory path for approval of such combination products may be 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 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) regulatory pathway for many of our potential pharmaceutical 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.

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.

*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.

## Edgar Filing: ANTARES PHARMA INC - Form 10-Q

*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**

*Together, certain of our stockholders own or have the right to acquire a significant portion of our stock and could ultimately control decisions regarding our company and impact our stock price*

As a result of our reverse business combination with Permaterc in January 2001 and subsequent additional debt and equity financings, Permaterc Holding AG and its controlling stockholder, Dr. Jacques Gonella, own a substantial portion (as of October 31, 2007, approximately 14%) of our outstanding shares of common stock. Dr. Gonella, who is the Chairman of our Board of Directors, also owns warrants to purchase an aggregate of 4,198,976 shares of common stock and options to purchase 144,500 shares of common stock. Additionally, three investors (Perceptive Life Sciences Fund, SCO Capital Group and SDS Funds) own warrants that are, as of October 31, 2007, exercisable into an aggregate of 5,286,588 shares of our common stock. Some of these investors also directly own shares of our common stock. If Dr. Gonella and all of the above investors exercised all of the warrants and options owned by them, Dr. Gonella would own approximately 18%, and the four investors as a group would own, at a minimum, over 7%, of our common stock.

Because the parties described above either currently own or could potentially own a large portion of our stock, they may be able to generally determine or they may be able to significantly influence the outcome of corporate actions requiring stockholder approval. As a result, these parties may be in a position to control matters affecting our company, including decisions as to our corporate direction and policies; future issuances of certain securities; our incurrence of debt; amendments to our certificate of incorporation and bylaws; payment of dividends on our common stock; and acquisitions, sales of our assets, mergers or similar transactions, including transactions involving a change of control. As a result, some investors may be unwilling to purchase our common stock. In addition, if the demand for our common stock is reduced because of these stockholders' control of the Company, the price of our common stock could be adversely affected. Additionally, future sales of large blocks of our common stock by any of the above investors could substantially adversely affect our stock price.

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

As of October 31, 2007, we have warrants outstanding that are exercisable, at prices ranging from \$0.55 per share to \$5.00 per share, for an aggregate of approximately 23,140,000 shares of our common stock. We also have options outstanding that are exercisable, at exercise prices ranging from \$0.70 to \$14.70 per share, for an aggregate of approximately 5,600,000 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.

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

As of October 31, 2007, our officers and directors beneficially owned an aggregate of approximately 19,400,000 shares (or approximately 27%) 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

<u>Exhibit No.</u>	<u>Description</u>
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, 2007

Jack E. Stover

President and Chief Executive Officer

/s/ Jack E. Stover

November 13, 2007

Robert F. Apple

Senior Vice President and Chief Financial Officer

/s/ Robert F. Apple