

OSCIENT PHARMACEUTICALS CORP

Form 10-Q

May 12, 2008

[Table of Contents](#)

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

**FORM 10-Q**

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES AND EXCHANGE ACT OF 1934**

For the Quarterly Period Ended: March 31, 2008

.. **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission File No: 0-10824

**OSCIENT PHARMACEUTICALS CORPORATION**

(Exact name of registrant as specified in its charter)

Edgar Filing: OSCIENT PHARMACEUTICALS CORP - Form 10-Q

**MASSACHUSETTS**  
(State or other jurisdiction of  
incorporation or organization)

**04-2297484**  
(I.R.S. Employer  
Identification no.)

**1000 WINTER STREET, SUITE 2200**

**WALTHAM, MASSACHUSETTS**  
(Address of principal executive offices)

**02451**  
(Zip code)

**Registrant's telephone number: (781) 398-2300**

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer  (do not check if smaller reporting company)

Smaller Reporting Company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

**COMMON STOCK**  
**\$0.10 PAR VALUE**

**14,125,127 Shares**  
**Outstanding May 2, 2008**

---

**Table of Contents**

**OSCIENT PHARMACEUTICALS CORPORATION**

**INDEX TO FINANCIAL INFORMATION AND OTHER INFORMATION**

	<b>Page</b>
<b><u>Part I. Financial Information (unaudited):</u></b>	
<u>Consolidated Balance Sheets as of March 31, 2008 and December 31, 2007</u>	3
<u>Consolidated Statements of Operations for the Three-Months Ended March 31, 2008 and March 31, 2007</u>	4
<u>Consolidated Statements of Cash Flows for the Three-Months Ended March 31, 2008 and March 31, 2007</u>	5
<u>Notes to Consolidated Financial Statements</u>	6
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	19
<u>Quantitative and Qualitative Disclosures about Market Risk</u>	32
<u>Controls and Procedures</u>	32
<b><u>Part II. Other Information:</u></b>	
<u>Legal Proceedings</u>	33
<u>Risk Factors</u>	33
<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	49
<u>Defaults Upon Senior Securities</u>	49
<u>Submission of Matters to a Vote of Security Holders</u>	49
<u>Other Information</u>	49
<u>Exhibits</u>	49
<u>Signature</u>	50
<u>Exhibit Index</u>	51

**Table of Contents****PART I FINANCIAL INFORMATION****ITEM 1: FINANCIAL STATEMENTS****OSCIENT PHARMACEUTICALS CORPORATION****CONSOLIDATED BALANCE SHEETS****(in thousands, except per share data)**

	<b>March 31, 2008 (unaudited)</b>	<b>December 31, 2007</b>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 37,913	\$ 48,268
Notes receivable	65	486
Accounts receivable (net of allowance for bad debts of \$35 in 2008 and 2007, respectively)	10,625	15,032
Inventories, net	7,361	9,059
Prepaid expenses and other current assets	3,646	2,886
Total current assets	59,610	75,731
Property and Equipment, at cost:		
Manufacturing and computer equipment	4,481	4,695
Equipment and furniture	579	564
Leasehold improvements	168	138
	5,228	5,397
Less Accumulated depreciation	4,478	4,590
	750	807
Restricted cash	4,198	4,198
Other assets	5,231	5,585
Intangible assets, net	108,626	110,903
Goodwill	76,960	76,960
Total Assets	\$ 255,375	\$ 274,184

**LIABILITIES AND SHAREHOLDERS EQUITY**

Current Liabilities:		
Short term obligations	\$ 13,337	\$ 38
Accounts payable	9,489	10,262
Accrued expenses and other current liabilities	23,130	20,928
Current portion of accrued facilities impairment charge	2,642	2,128
Deferred revenue	364	364
Total current liabilities	48,962	33,720
Long-term liabilities:		
Long-term obligations, net of current maturities	244,060	252,859
Noncurrent portion of accrued facilities impairment charge	7,849	8,831
Other long-term liabilities	3,780	7,216
Deferred revenue	182	273
Shareholders Deficit:		

Edgar Filing: OSCIENT PHARMACEUTICALS CORP - Form 10-Q

Common stock, \$0.10 par value Authorized 174,375 shares, Issued and Outstanding 14,125 and 13,892 in 2008 and 2007, respectively	1,413	1,389
Series B restricted common stock, \$0.10 par value Authorized 625 shares, Issued and outstanding none		
Additional paid-in-capital	416,303	415,654
Accumulated deficit	(467,174)	(445,758)
Total shareholders deficit	(49,458)	(28,715)
Total Liabilities and Shareholders Deficit	\$ 255,375	\$ 274,184

The accompanying notes are an integral part of these consolidated financial statements.

**Table of Contents****OSCIENT PHARMACEUTICALS CORPORATION****CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)**

(in thousands, except per share data)

	Three-Months Ended	
	March 31, 2008	March 31, 2007
Revenues (net):		
Product Sales	\$ 18,269	\$ 22,043
Other	97	1,156
Total net revenues	18,366	23,199
Costs and expenses:		
Cost of product sales (1)	7,016	8,754
Research and development (1)	1,343	1,505
Selling and marketing (1)	19,752	17,455
General and administrative (1)	3,890	3,559
Total costs and expenses	32,001	31,273
Loss from operations	(13,635)	(8,074)
Other income (expense):		
Interest income	356	491
Interest expense	(8,314)	(4,478)
Gain on disposition of investment	317	158
Loss on derivatives	(44)	
Other income	8	49
Net other expense	(7,677)	(3,780)
Loss before income tax	(21,312)	(11,854)
Provision for income tax	(105)	(108)
Net loss	\$ (21,417)	\$ (11,962)
Net loss per common share:		
Basic and diluted	\$ (1.53)	\$ (0.88)
Weighted average common shares outstanding:		
Basic and diluted	13,968,741	13,581,618

(1) Includes non-cash stock-based compensation as follows:

Cost of product sales	\$ (13)	\$ 4
Research and development	9	
Selling and marketing	280	318
General and administrative	302	380

The accompanying notes are an integral part of these consolidated financial statements.



**Table of Contents****OSCIENT PHARMACEUTICALS CORPORATION****CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)**

(in thousands)

	<b>Three-Months Ended</b>	
	<b>March 31, 2008</b>	<b>March 31, 2007</b>
<b>Cash Flows from Operating Activities:</b>		
Net loss	\$ (21,417)	\$ (11,962)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,404	2,489
Provision for excess and obsolete inventories	220	130
Non-cash interest expense	3,616	350
Loss on derivatives	44	
Gain on disposition of investment	(317)	(158)
Stock based compensation	578	702
Changes in operating assets and liabilities:		
Accounts receivable	4,407	2,864
Inventories	1,478	2,665
Prepaid expenses and other current assets	(760)	(43)
Accounts payable	(773)	(1,805)
Accrued expenses and other liabilities	(617)	(1,483)
Deferred revenue	(91)	(399)
Accrued facilities impairment charge	(575)	(644)
Accrued other long-term liabilities	730	721
<b>Net cash used in operating activities</b>	<b>(11,073)</b>	<b>(6,573)</b>
<b>Cash Flows from Investing Activities:</b>		
Proceeds from disposition of investment	317	158
Proceeds from repayments of notes receivable	421	173
Purchases of property and equipment	(70)	
Increase in other assets	(35)	(240)
Increase in restricted cash		(191)
Proceeds from sale of property and equipment		2
<b>Net cash provided by (used in) investing activities</b>	<b>633</b>	<b>(98)</b>
<b>Cash Flows from Financing Activities:</b>		
Proceeds from issuance of stock under the employee stock purchase plan	94	360
Payments on long-term obligations	(9)	(9)
Proceeds from exercise of stock options		9
<b>Net cash provided by financing activities</b>	<b>85</b>	<b>360</b>
<b>Net Decrease in Cash and Cash Equivalents</b>	<b>(10,355)</b>	<b>(6,311)</b>
<b>Cash and Cash Equivalents, beginning of period</b>	<b>48,268</b>	<b>38,196</b>
<b>Cash and Cash Equivalents, end of period</b>	<b>\$ 37,913</b>	<b>\$ 31,885</b>

The accompanying notes are an integral part of these consolidated financial statements.





**Table of Contents**

**OSCIENT PHARMACEUTICALS CORPORATION**

**Notes to Consolidated Financial Statements**

**(Unaudited)**

**(1) Operations and Basis of Presentation**

Oscient Pharmaceuticals Corporation (the Company) is a commercial-stage pharmaceutical company marketing Food and Drug Administration (FDA)-approved products in the United States. The Company's strategy is to grow the sales of its existing products and to gain access to new products via transactions, including acquisition, in-licensing and co-promotion. Oscient has developed a commercial infrastructure, including a national sales force calling on targeted primary care physicians, cardiologists, endocrinologists and pulmonologists in the United States.

Oscient currently markets two products: ANTARA® (fenofibrate) capsules, a cardiovascular product, and FACTIVE® (gemifloxacin mesylate) tablets, a fluoroquinolone antibiotic. ANTARA is approved by the FDA to treat hypercholesterolemia (high blood cholesterol) and hypertriglyceridemia (high triglycerides) in combination with a healthy diet. The Company licenses the rights to ANTARA from Ethypharm S.A. of France (Ethypharm). The Company began promoting ANTARA in late August 2006. FACTIVE is indicated for the treatment of community-acquired pneumonia of mild to moderate severity (CAP) and acute bacterial exacerbations of chronic bronchitis (AECB). The Company licenses the rights to gemifloxacin, the active ingredient in FACTIVE tablets, from LG Life Sciences of the Republic of Korea (LG Life Sciences). The Company launched FACTIVE in the U.S. market in September 2004.

Additionally, the Company has a novel, late-stage antibiotic candidate, Ramoplanin, for the treatment of *Clostridium difficile*-associated disease. The Company has made the strategic decision to concentrate its financial resources on building its revenues for products promoted to community-based physicians in the United States and is currently seeking to out-license, co-develop or sell its rights to Ramoplanin to a partner.

As shown in the consolidated financial statements, at March 31, 2008, the Company has total cash, cash equivalents and restricted cash balance of approximately \$42,111,000, which includes approximately \$4,198,000 in restricted cash, and an accumulated deficit of approximately \$467,174,000. Based on the Company's available capital, anticipated cash generated from operations and management's ability to manage expenses, the Company believes that the cash on hand as of March 31, 2008, is sufficient to fund continuing operations through at least the end of the first quarter of 2009. There is no assurance, however, that changes in our plans or events affecting our operations will not result in accelerated or unexpected expenditures. The Company most likely will need to raise additional capital within the next 12 months through the issuance of debt or equity securities and/or refinance its existing debt. The Company's ability to raise additional capital, however, will be heavily impacted by, among other factors, the investment market for biopharmaceutical companies and the progress of the ANTARA and FACTIVE commercial programs as well as the Company's progress in meeting its operational and financial objectives, acquiring, licensing or co-promoting an additional product and developing a partnership to advance the Ramoplanin clinical development program. Additional financing may not be available to the Company when needed, or, if available, may not be available on favorable terms. If the Company cannot obtain adequate financing on acceptable terms when such financing is required, the Company's business will be adversely affected.

These consolidated financial statements have been prepared by the Company without audit, pursuant to the rules and regulations of the Securities and Exchange Commission. In the opinion of the Company's management, the unaudited consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements and include all adjustments (consisting only of normal recurring adjustments) necessary for a fair presentation of results for the interim periods. Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. The Company believes, however, that its disclosures are adequate to make the information presented not misleading. The accompanying consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and related footnotes for the year ended December 31, 2007 which are included in the Company's Annual Report on Form 10-K. Such Annual Report on Form 10-K was filed with the Securities and Exchange Commission on February 6, 2008.

**(2) Summary of Significant Accounting Policies**

The accompanying consolidated financial statements reflect the application of certain accounting policies, as described in this note and elsewhere in the accompanying notes to the consolidated financial statements.

---

## **Table of Contents**

### **(a) Revenue Recognition**

The Company's principal source of revenue is the sale of ANTARA capsules and FACTIVE tablets. ANTARA revenue results are anticipated to be steady throughout the fiscal year. The Company expects demand for FACTIVE to be highest from December to March as the incidence of respiratory tract infections, including CAP and AECB, tends to increase during the winter months. In addition, fluctuations in the severity of the annual respiratory tract infection season may cause product sales to vary from year to year. Due to these seasonal fluctuations in demand for FACTIVE, the Company's results in any particular quarter may not be indicative of the results for any other quarter or for the entire year.

#### *Product Sales*

The Company follows the provisions of Staff Accounting Bulletin (SAB) No. 104, Revenue Recognition (a replacement of SAB No. 101) (SAB No. 104) and recognizes revenue from product sales upon delivery of product to wholesalers, when persuasive evidence of an arrangement exists, the fee is fixed or determinable, title to product and associated risk of loss has passed to the wholesaler and collectability of the related receivable is reasonably assured. All revenues from product sales are recorded net of applicable allowances for sales returns, rebates, special promotional programs, and discounts. For arrangements where the risk of loss has not passed to wholesalers or pharmacies, the Company defers the recognition of revenue by recording deferred revenue until such time that risk of loss has passed. The cost of ANTARA and FACTIVE associated with amounts recorded as deferred revenue is recorded in inventory until such time as risk of loss has passed.

#### *Other Revenue*

Other revenues primarily consist of sublicensing revenues related to FACTIVE. The Company recognizes revenue in accordance with SAB No. 104 and Emerging Issues Task Force (EITF) Issue No. 00-21, Revenue Arrangements with Multiple Deliverables (EITF No. 00-21). In accordance with EITF No. 00-21, the up-front license payments related to the various sublicense agreements will be recognized as revenue over the term of the Company's continuing obligations under the arrangements which range from eighteen months to thirty-three months. Substantive milestones achieved are recognized as revenue when earned and when payment is reasonably assured, if the Company has completed its remaining obligations under the arrangement. If the Company has further obligations, milestone payments are recognized as revenue if the Company has sufficient evidence of fair value for its remaining obligations otherwise the milestone payment is recognized as revenue over the remaining performance period. The Company expenses incremental direct costs associated with sublicense agreements in the period in which the expense is incurred.

On August 1, 2006, the Company announced that it received notice from Pfizer Mexico that FACTIVE was approved by the Ministry of Health in Mexico to be marketed as FACTIVE-5 for the treatment of community-acquired pneumonia, acute bacterial exacerbations of chronic bronchitis and acute bacterial sinusitis which generated a milestone payment recognized as revenue in 2006. On January 4, 2007, the Company announced that it had granted commercialization rights to FACTIVE in Europe to Menarini International Operation Luxembourg S.A. (Menarini), a wholly-owned subsidiary of Menarini Industrie Farmaceutiche Riunite S.r.l. Part of this arrangement included an up-front license payment which the Company is recognizing over the term of the Company's obligations under the arrangement. On March 2, 2007, the Company announced that Abbott Laboratories, Ltd. (Abbott Canada), the Canadian affiliate of Abbott Laboratories, had received approval to begin the promotion of FACTIVE in Canada. In connection with the terms of the agreement with Abbott, a milestone payment related to regulatory approval of the Company's manufacture of FACTIVE for Canada was recorded as other revenue during 2007. The Company subsequently amended the agreement on January 31, 2008 whereby Abbott Canada's development and commercialization obligations were substantially reduced. The amendment also provides that the Company can terminate the agreement at any time with prior notice to Abbott Canada and Abbott Canada can terminate with prior notice to the Company after November 30, 2008.

### **(b) Sales Rebates, Discounts and Incentives**

The Company's sales of ANTARA and FACTIVE in the U.S. are made to pharmaceutical wholesalers for further distribution through pharmacies to the ultimate consumers of the product. When the Company delivers its product, the Company reduces the amount of gross revenue recognized from such product sales based primarily on estimates of four categories of discounts and allowances that suggest that all or part of the revenue should not be recognized at the time of the delivery product returns, cash discounts, rebates, and special promotional programs.

#### *Product Returns*

Factors that are considered in the Company's estimate of future ANTARA and FACTIVE product returns include an analysis of the amount of product in the wholesaler and pharmacy channel, review of consumer consumption data as reported by external information management companies, actual and historical return rates for expired lots, the remaining time to



**Table of Contents**

expiration of the product, and the forecast of future sales of the Company's product. Consistent with industry practice, the Company offers contractual return rights that allow its customers to return product within six months prior to, and twelve months subsequent to, the expiration date of the product. ANTARA capsules and FACTIVE tablets each have a 36-month expiration period from the date of manufacturing. As of March 31, 2008 and December 31, 2007, the Company's product return reserve was approximately \$3,600,000 and \$3,169,000, respectively. This reserve is evaluated on a quarterly basis, assessing each of the factors described above, and adjusted accordingly. Based on the factors noted above, the Company believes its estimate of product returns is reasonable, and changes, if any, from this estimate would not have a material impact to the Company's financial statements.

*Cash Discounts*

The Company's standard invoice includes a contractual cash 2% discount, net 30 days terms. Based on historical experience, the Company estimates that most of its customers deduct a 2% discount from their balance. The cash discount reserve is presented as an allowance against trade receivables in the accompanying consolidated balance sheets. As of March 31, 2008 and December 31, 2007, the balance of the cash discounts reserve was approximately \$195,000 and \$343,000 respectively.

*Rebates*

The liability for commercial managed care rebates is calculated based on historical and current rebate redemption and utilization rates with respect to each commercial contract. The liability for Medicaid rebates is calculated based on historical and current rebate redemption and utilization rates contractually submitted by each state. As of March 31, 2008 and December 31, 2007, the balance of the accrual for managed care and Medicaid rebates for ANTARA and FACTIVE in total was approximately \$3,319,000 and \$4,263,000, respectively. Considering the estimates made by the Company, as well as estimates reflected in third party utilization reports that are used in evaluating the required liability balance, the Company believes its estimates are reasonable.

*Special Promotional Programs*

The Company, from time to time, offers certain promotional incentives to its customers for both ANTARA and FACTIVE and will continue this practice in the future. Such programs include: sample cards to retail consumers, certain product incentives to pharmacy customers, and other sales stocking allowances. The Company accounts for these programs in accordance with EITF No. 01-09, Accounting for Consideration Given by a Vendor to a Customer (EITF No. 01-09). Examples of programs utilized to date are as follows:

*Voucher Rebate Programs for ANTARA*

Since acquiring ANTARA in August 2006, the Company has initiated four voucher rebate programs for ANTARA whereby the Company offered a point-of-sale rebate to retail consumers. The liabilities the Company recorded for these voucher rebate programs were estimated based upon the historical rebate redemption rates for similar completed programs by other pharmaceutical companies as reported to the Company by a third party claims processing organization and actual redemption rates on completed programs by the Company. The first program expired on December 31, 2006, the second program expired on September 30, 2007, the third program expires on February 28, 2009 and the fourth program expires on March 31, 2009. As of March 31, 2008 and December 31, 2007, the balance of the liabilities for these voucher programs totaled approximately \$383,000 and \$491,000, respectively.

*Voucher Rebate Programs for FACTIVE*

The Company periodically initiates voucher rebate programs for FACTIVE whereby the Company offers point-of-sale rebates to retail consumers. The liabilities the Company records for these voucher rebate programs are estimated based upon the historical rebate redemption rates for similar completed programs. In April 2007, the Company initiated a voucher rebate program whereby the Company offered a point-of-sale rebate to retail consumers. This program expired on December 31, 2007. In October 2007, the Company initiated another voucher rebated program whereby the Company offered a point-of-sale rebate to retail consumers. This program expires on April 30, 2008. As of March 31, 2008 and December 31, 2007, the balance of the liabilities for these voucher programs totaled approximately \$1,254,000 and \$1,396,000, respectively.

**(c) Accounts Receivable**

Trade accounts receivable consists of amounts due from wholesalers for the purchase of ANTARA and FACTIVE. Accounts receivable related to sales of FACTIVE are the accounts receivable of the Company and accounts receivable related to sales of ANTARA are the accounts receivable of Guardian II Acquisition Corporation (Guardian II) (the entity which holds all of the ANTARA assets), a wholly-owned subsidiary

## Edgar Filing: OSCIENT PHARMACEUTICALS CORP - Form 10-Q

of the Company. Guardian II granted Paul Royalty Fund Holdings II, LP, an affiliate of Paul Capital Partners (Paul Capital), a security interest in substantially all of its assets, including its accounts receivable, to secure its obligations to Paul Capital. See Note 7.

**Table of Contents**

The Company performs ongoing credit evaluations on its customers and collateral is generally not required. As of March 31, 2008 and December 31, 2007, the Company had reserved approximately \$35,000 for bad debts related to the sale of ANTARA or FACTIVE. The Company continuously reviews all customer accounts to determine if an allowance for uncollectible accounts is necessary. The Company currently provides substantially all of its distributors with payment terms of up to 30 days on purchases of ANTARA and FACTIVE. Amounts past due from customers are determined based on contractual payment terms. Through March 31, 2008, payments have generally been made in a timely manner and the Company has not written off any customer accounts receivable balances. The Company has not provided a reserve balance related to other non-trade receivables as of March 31, 2008 and December 31, 2007.

The following table represents accounts receivable (in thousands):

	As of March 31, 2008	As of December 31, 2007
Trade, net	\$ 10,561	\$ 14,950
Other, net	64	82
<b>Total</b>	<b>\$ 10,625</b>	<b>\$ 15,032</b>

**(d) Restricted Cash**

At March 31, 2008 and December 31, 2007, approximately \$3,697,000 of cash is restricted in connection with a letter of credit issued for the building lease at the Company's South San Francisco, California facility, approximately \$433,000 of cash is restricted in connection with a letter of credit issued for the building lease at the Company's Waltham, Massachusetts facility and approximately \$68,000 of cash is restricted in connection with a letter of credit issued for the building lease at the Company's Skillman, New Jersey facility. The restrictions related to the South San Francisco facility, the Waltham facility and the Skillman facility expire on February 28, 2011, March 31, 2012 and June 30, 2013, respectively.

**(e) Inventories**

Inventories are stated at the lower of cost or market value, with cost determined under the average cost method which approximates actual cost. Products are removed from inventory on a first-in-first-out basis and recognized as cost of goods sold on an average cost basis.

On a quarterly basis, the Company analyzes inventory levels, and provides a reserve for inventory and marketing samples that have become obsolete, have a cost basis in excess of their expected net realizable value or are in excess of forecast requirements to cost of product revenues and marketing expense, respectively. Expired inventory is disposed of and the related costs are written off against the previously established reserves.

At March 31, 2008 and December 31, 2007, there was approximately \$934,000 and \$1,088,000 in ANTARA sample product to be used for ANTARA marketing programs and approximately \$892,000 and \$655,000 in FACTIVE sample product to be used for FACTIVE marketing programs. These are classified as other current assets in the accompanying consolidated balance sheets.

The following table represents net trade inventories (in thousands):

	As of March 31, 2008	As of December 31, 2007
Raw material	\$ 722	\$ 2,846
Work-in-process	3,674	3,022
Finished goods	2,965	3,191
<b>Total</b>	<b>\$ 7,361</b>	<b>\$ 9,059</b>

**(f) Net Loss Per Share**

Basic and diluted net loss per share was determined by dividing net loss by the weighted average shares outstanding during the period. Diluted loss per share is the same as basic loss per share for all periods presented, as the effect of the potential common stock is anti-dilutive. Anti-dilutive securities which consist of stock options, convertible notes, warrants



## **Table of Contents**

and unvested restricted stock that are not included in calculating the net loss per share, totaled 20,896,927 and 6,612,480 shares (prior to the application of the treasury stock method) during the three-month periods ended March 31, 2008 and 2007, respectively.

### **(g) Single Source Suppliers**

#### *FACTIVE*

The Company currently obtains the active pharmaceutical ingredient (API) for its commercial requirements for FACTIVE from LG Life Sciences. The Company purchases the active pharmaceutical ingredient pursuant to a long-term supply agreement. The disruption or termination of the supply of the commercial requirement for FACTIVE or a significant increase in the cost of the active pharmaceutical ingredient from this source could have a material adverse effect on the Company's business, financial position and results of operations.

#### *ANTARA*

Pursuant to the Company's license arrangement with Ethypharm, Ethypharm is responsible for the manufacture and supply of ANTARA finished product or ANTARA bulk product at the Company's option. The disruption or termination of the supply of ANTARA by Ethypharm or its third party contractors could have a material adverse effect on the Company's business, financial position and results of operations.

### **(h) Use of Estimates**

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. These estimates include the following: reserves for inventory obsolescence, sales and managed care rebate reserves, reserves pertaining to special promotional programs, product returns reserves and the useful lives and expected future cash flows for intangible assets.

### **(i) Financial Instruments**

The estimated fair value of the Company's financial instruments, including cash, cash equivalents and accounts receivable, approximates the carrying values of these instruments.

In connection with financing the acquisition of ANTARA, the Company recognized an embedded derivative instrument related to a put/call liability. In connection with the convertible debt exchange, the Company recognized an embedded derivative instrument related to an interest make-whole provision. Both are recognized in the accompanying consolidated financial statements at fair value and are recorded as other long-term liabilities in the accompanying consolidated balance sheets. Changes in fair value are recorded in the accompanying consolidated statements of operations. See Note 4.

### **(j) Comprehensive Loss**

The Company follows the provisions of Statement of Financial Accounting Standards (SFAS) No. 130, Reporting Comprehensive Income (SFAS No. 130). SFAS No. 130 requires disclosure of all components of comprehensive loss on an annual and interim basis. Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. For the three-month periods ended March 31, 2008 and 2007, the net loss is equal to the comprehensive loss.

### **(k) Long-Lived Assets**

The Company follows the provisions of SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets (SFAS No. 144). Under SFAS No. 144, long-lived assets and identifiable intangible assets with finite lives are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If indicators of impairment exist, recoverability of assets to be held and used is assessed by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. Recoverability measurement and estimating the undiscounted cash flows is done at the lowest possible level for which there are identifiable assets. If the aggregate undiscounted cash flows are less than the carrying value of the asset, then the resulting impairment charge to be recorded is calculated based on the amount by which the carrying amount of the asset exceeds its fair value. Any write-downs are recorded as permanent reductions in the carrying amount of the asset.



**Table of Contents**

During 2007, events and circumstances, primarily a reduction in projected long term cash flows, indicated that the FACTIVE intangible asset could become impaired. However, at December 31, 2007, the Company's estimate of undiscounted cash flows indicated that such carrying amounts are expected to be recovered and therefore the assets are not impaired. As a result of the reduction of the projected long term cash flows at the end of 2007, the Company reviewed and updated its cash flow projections as of March 31, 2008, which indicated that the carrying amounts are expected to be recovered and therefore the intangible assets of FACTIVE are not impaired. Nonetheless, it is reasonably possible that the estimate of undiscounted cash flows may change in the near term resulting in the need to write down the intangible asset associated with FACTIVE to fair value. The Company's estimate of undiscounted cash flows is based upon several significant assumptions including, but not limited to, estimated domestic sales growth, the ability to significantly penetrate international markets and the ability to satisfy its minimum requirements under the agreement with the licensor, LG Life Science.

The Company also follows the provisions of SFAS No. 142, Goodwill and Other Intangible Assets, (SFAS No. 142). Under SFAS No. 142, goodwill and purchased intangible assets with indefinite lives are not amortized but are reviewed periodically for impairment. The Company performs an annual evaluation of goodwill at the end of each fiscal year to test for impairment or more frequently if events or circumstances indicate that goodwill may be impaired. Because the Company has a single operating segment, which is its sole reporting unit, the Company performs this test by comparing the fair value of the entity as measured by the quoted market price of its common stock with its book value, including goodwill, which at present is a deficit. If the fair value exceeds the book value, goodwill is not impaired. If the book value exceeds the fair value, then the Company would calculate the potential impairment loss by comparing the implied fair value of goodwill with the book value. If the implied fair value of goodwill is less than the book value, then an impairment charge would be recorded.

As of March 31, 2008, the Company does not believe that any of its long-lived assets, goodwill, or intangible assets are impaired.

**(l) Stock-Based Compensation**

The Company records stock-based compensation expense in accordance with SFAS No. 123 (Revised 2004), Share-Based Payment (SFAS No. 123R). SFAS No. 123R requires companies to expense the fair value of employee stock options and other forms of stock-based employee compensation over the employees' service periods. Compensation cost is measured at the fair value of the award at the grant date, including estimated forfeitures, and is adjusted to reflect actual forfeitures and the outcomes of certain conditions. See Note 5.

**(m) Income Taxes**

The Company applies SFAS No. 109, Accounting for Income Taxes (SFAS No. 109), which requires the Company to recognize deferred tax assets and liabilities for expected future tax consequences of events that have been recognized in the financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using the enacted tax rates in effect for the year in which the differences are expected to reverse. SFAS No. 109 requires deferred tax assets and liabilities to be adjusted when the tax rates or other provisions of the income tax laws change.

In accordance with FASB Interpretation No. 48 Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement No. 109 (the Interpretation) (FIN 48), the Company's historical practice was and will continue to be to recognize any interest and penalties related to unrecognized tax benefits in income tax expense. As of March 31, 2008, there were no unrecognized tax benefits, and as such, the Company has not recorded interest and penalties related to unrecognized tax benefits.

The Company's income tax expense of approximately \$105,000 and \$108,000 for the three-month periods ending March 31, 2008 and 2007, respectively, is comprised of deferred federal and state taxes which relates to the tax effects of the Company's indefinite lived intangible that cannot be offset against the Company's deferred tax assets.

The Company files income tax returns in the U.S. federal and various state jurisdictions. The Company is generally no longer subject to income tax examinations by U.S. federal, state and local tax authorities for years before 1992.

**(n) Recent Accounting Pronouncements**

*Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133*

In March 2008, the Financial Accounting Standard Board (FASB) issued FASB Statement No. 161, Disclosures about Derivative Instruments and Hedging Activities (SFAS No. 161). SFAS No. 161 requires entities to provide greater transparency about (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for under SFAS No. 133 and its related interpretations, and (c) how derivative instruments and related hedged items affect an entity's financial



**Table of Contents**

position, results of operations, and cash flows. SFAS No. 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. Management is in the process of studying the impact of this standard on the Company's financial accounting and reporting.

*Business Combinations*

In December 2007, the FASB issued Statement No. 141R, *Business Combinations* (SFAS No. 141R). SFAS No. 141R improves consistency and comparability of information about the nature and effect of a business combination by establishing principles and requirements for how an acquirer (a) recognizes and measures in its financial statements the identifiable assets acquired, liabilities assumed and any non-controlling interest in the acquiree; (b) recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase; and (c) determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. SFAS No. 141R applies prospectively to all business combination transactions for which the acquisition date is on or after January 1, 2009. The impact of the Company's adoption of SFAS No. 141R will depend upon the nature and terms of business combinations, if any, that the Company consummates on or after January 1, 2009.

*Accounting for Collaborative Arrangements*

In November 2007, the EITF issued EITF Issue No. 07-01 *Accounting for Collaborative Arrangements* (EITF No. 07-01). EITF No. 07-01 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable generally accepted accounting principles (GAAP) or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. Further, EITF No. 07-01 clarified that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to Issue 01-9, *Accounting for Consideration Given by a Vendor to a Customer* EITF No. 07-01 is effective for fiscal years beginning after December 15, 2008. The Company has not yet completed its evaluation of EITF No. 07-01, but does not currently believe that it will have a material impact on the results of operations, financial position or cash flows.

**(3) Restructuring Plans**

At the time of acquisition of GeneSoft Pharmaceuticals (Genesoft) in 2004, management approved a plan to integrate certain Genesoft facilities into existing operations. In connection with the integration activities, the Company included in the purchase price allocation a restructuring liability of approximately \$18,306,000, which includes \$1,419,000 in severance-related costs and \$16,887,000 in facility lease impairment costs pertaining to 68,000 square feet of leased space which expires on February 28, 2011.

The following table summarizes the liability activity related to the Genesoft acquisition during the three-month period ended March 31, 2008 (in thousands):

	Balance at December 31, 2007	Cash Payments	Interest Accretion	Balance at March 31, 2008
Assumed facility lease liability	\$ 10,959	\$ (575)	\$ 107	\$ 10,491

**(4) Fair Value Measurements**

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* (SFAS No. 157). SFAS No. 157 defines fair value, establishes a framework for measuring fair value in accordance with GAAP and expands disclosures about fair value measurements. SFAS No. 157 codifies the definition of fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, clarifies the principle that fair value should be based on the assumptions market participants would use when pricing the asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007 and interim periods within those years. The Company adopted SFAS No. 157 on January 1, 2008. The three levels of the fair value hierarchy under SFAS No. 157 are described below:

## Edgar Filing: OSCIENT PHARMACEUTICALS CORP - Form 10-Q

Level 1 Relates to observable inputs such as quoted prices in active markets that are accessible at the measurement date for identical assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

**Table of Contents**

**Level 2** Relates to other inputs that are observable, directly or indirectly, such as quoted prices for similar assets and liabilities or market corroborated inputs.

**Level 3** Relates to unobservable inputs used when little or no market data is available and require the Company to develop its own assumptions about how market participants would price the assets or liabilities. The fair value hierarchy gives the lowest priority to Level 3 inputs.

The primary objective of the Company's investment activities is to preserve principal and fulfill liquidity needs while at the same time maximizing the income the Company receives from the Company's investments without significantly increasing risk. To achieve this objective, the Company maintains the majority of its portfolio of cash equivalents in money market funds to maximize investment income and minimize investment risk. As of March 31, 2008, the Company believes that its cash equivalents reflect the carrying value which is not subject to any loss or write-down.

As of March 31, 2008, the Company's cash equivalents were classified as level 1 assets where inputs are quoted in active markets for identical assets or liabilities that the Company has the ability to access the measurement date. An active market for the Company's cash equivalents is available in which transactions for the asset occur with sufficient frequency and volume which provide pricing information on an ongoing basis.

For derivative liabilities that use Level 2 inputs, the Company utilizes information obtained directly from observable market inputs which include the Company's stock price, volatility, market value of debt and risk free interest rate. For derivative liabilities that use Level 3 inputs, the Company developed its own assumptions and decision point related to a put/call premium that does not have any observable inputs or available market data to support the fair value.

The following table represents, by level within the fair value hierarchy, a summary of the fair market value of assets and liabilities the Company held as of March 31, 2008 (in thousands):

<b>March 31, 2008</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>Assets:</b>				
Cash equivalents	\$ 35,828	\$	\$	\$ 35,828
<b>Liabilities:</b>				
Derivative Liabilities	\$	\$ 153,000	\$ 944,000	\$ 1,097,000

The reconciliation of the Company's liabilities measured at fair value on a recurring basis using unobservable inputs (Level 3) is as follows:

	<b>Derivative Liability</b>
Balance at January 1, 2008	\$ 986,000
Gain reported in statement of operations	42,000
<b>Balance at March 31, 2008</b>	<b>\$ 944,000</b>

**(5) Stockholder's Equity****Equity Plans**

The Company granted stock options to key employees and consultants under its 1991, 1993, 1995 and 1997 Stock Option Plans, and continues to grant stock-based awards under its 2001 Incentive Plan (collectively, the Option Plans). On August 13, 2007, the Board of Directors approved the Company's 2007 Employment Inducement Award Plan (the 2007 Inducement Plan) and authorized 500,000 shares of Common Stock for issuance under the 2007 Inducement Plan. The Compensation Committee of the Board of Directors determines the purchase price and vesting schedule applicable to each option grant. As of March 31, 2008, there were no shares reserved for future grants under the 1991, 1993, 1995 and 1997 Plans. The 2001 Incentive Plan, as amended and restated, provides for the grant of non-qualified stock options, incentive stock options,

## Edgar Filing: OSCIENT PHARMACEUTICALS CORP - Form 10-Q

restricted stock, stock appreciation rights, unrestricted stock, deferred stock, convertible securities, and cash and equity-based performance awards. The 2007 Inducement Plan provides for the grant of non-qualified stock options and restricted stock. As of March 31, 2008, 1,695,372 shares were authorized and 105,759 shares were available for future issuance under the 2001 Incentive Plan and 500,000 shares were authorized and 97,285 shares were available for future



**Table of Contents**

issuance under the 2007 Inducement Plan. In addition, under separate agreements not covered by any plan, the Company has granted certain key employees and directors of the Company an aggregate of 65,506 options to purchase common stock. The Company also has an Employee Stock Purchase Plan (ESPP), which was adopted in February 2000. As of March 31, 2008, 431,250 shares were authorized and 77,103 shares were available for future issuance under this plan.

**Stock-Based Compensation**

The Company accounts for all employee share-based payments, including grants of stock options, restricted stock and stock issued under the ESPP, in accordance with SFAS No. 123 (Revised 2004), Share-Based Payment (SFAS No. 123R).

The Company's policy is to recognize compensation cost for awards with service conditions and graded vesting using the straight-line method. Additionally, its policy is to issue authorized but previously unissued shares to satisfy share option exercises, the issuance of restricted stock and stock issued under the ESPP. The amount of stock-based compensation recognized during a period is based on the value of the portion of the awards that are ultimately expected to vest. In addition, the requisite service period is generally equal to the vesting term. SFAS No. 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The term forfeitures is distinct from cancellations or expirations and represents only the unvested portion of the surrendered option. Ultimately, the actual expense recognized over the vesting period will only be for those shares that vest.

Stock compensation expense recorded in the three-month periods ended March 31, 2008 and 2007 was \$578,000 and \$702,000, respectively. The compensation expense under SFAS No. 123R is recorded in cost of product sales, research and development expense, selling and marketing expense, and general and administrative expense based on the specific allocation of employees receiving the equity awards.

As of March 31, 2008, the Company estimates there is approximately \$3,435,000 of total unrecognized compensation cost related to unvested share based awards. These costs are expected to be recognized over a weighted average remaining requisite service period of 1.46 years. The Company expects approximately 866,000 in unvested options to vest at some point in the future. The value of options expected to vest is calculated by applying an estimated forfeiture rate to the unvested options.

**(6) Cash and Cash Equivalents**

The Company applies the provisions of SFAS No. 115, Accounting for Certain Investments in Debt and Equity Securities (SFAS No. 115). Cash equivalents are short-term, highly liquid investments with maturities of 90 days or less. Cash equivalents are carried at cost, which approximates fair value. The fair value of the Company's cash equivalents is determined based on market value. At March 31, 2008 and December 31, 2007, cash and cash equivalents totaled \$37,913,000 and \$48,268,000, respectively.

**(7) Long-Term Obligations**

Long-term obligations consist of the following (in thousands):

	As of March 31, 2008	As of December 31, 2007
3.5% Senior convertible promissory notes	\$ 182,557	\$ 179,508
3 1/2% Senior convertible promissory notes	829	829
5% Convertible promissory notes	13,300	13,300
Revenue interest assignment	40,589	39,129
12% Senior secured note	20,000	20,000
Capital lease	122	131
	257,397	252,897
Less short term obligations	13,337	38
	\$ 244,060	\$ 252,859

**(a) Debt Obligations**

## Edgar Filing: OSCIENT PHARMACEUTICALS CORP - Form 10-Q

On February 6, 2004, in connection with its merger with Genesoft, the Company issued approximately \$22,310,000 in principal amount of its 5% convertible five year promissory notes due February 2009 (the 2009 Notes ). Following the exchange offer completed in May 2007 described below, there are approximately \$13,300,000 principal amount of the 2009 Notes outstanding at March 31, 2008 which have been classified as short-term obligations on the accompanying consolidated balance sheets. The 2009 Notes are convertible into the Company s common stock at the option of the holders, at a conversion price of \$53.13 per share, as adjusted pursuant to the reverse stock split which the Company effectuated in November 2006.

---

**Table of Contents**

On June 26, 2004, the Company issued \$152,750,000 in principal amount of its 3 1/2% senior convertible promissory notes due in April 2011 (the Original 2011 Notes ). Following the exchange offer completed in May 2007 described below, there are approximately \$829,000 principal amount of the Original 2011 Notes outstanding at March 31, 2008. These notes are convertible into the Company's common stock at the option of the holders at a conversion price of \$53.14 per share, as adjusted pursuant to the reverse stock split which the Company effectuated in November 2006. The Company may not redeem the outstanding Original 2011 Notes at its election before May 10, 2010. After this date, the Company can redeem all or a part of the Original 2011 for cash at a price equal to 100% of the principal amount of the notes to be redeemed plus accrued and unpaid interest. The holders' right of repurchase under the Original 2011 Notes is identical to the right of repurchase under the New Notes (defined below) and is described below.

In May 2007, the Company completed (i) an exchange offer with certain holders of the Original 2011 Notes in which the Company exchanged \$151,921,000 aggregate principal amount of its new 3.50% Convertible Senior Notes due 2011 (the New Notes ) for \$151,921,000 aggregate principal amount of its then outstanding Original 2011 Notes; and (ii) an exchange offer with holders of the 2009 Notes in which the Company exchanged approximately \$10,574,000 aggregate principal and accrued interest amounts of its then outstanding 2009 Notes for approximately \$13,746,000 aggregate principal amount of the New Notes. The Company also issued an additional \$60,000,000 of New Notes to the public for cash at a public offering price of 77.5% of principal, resulting in \$46,500,000 in gross proceeds to the Company.

The New Notes are initially convertible into approximately 16,718,000 common shares at a conversion rate of 74.074 shares of the Company's common stock per \$1,000 principal amount of New Notes, which is equivalent to a conversion price of approximately \$13.50 per share. The New Notes are convertible at any time by the holder. In the event of a fundamental change, holders of the Original 2011 Notes and the New Notes have the right to require the Company to repurchase all or any portion of their notes at a price equal to 100% of the principal amount plus accrued and unpaid interest. Under the indenture for the Original 2011 Notes and the New Notes, a fundamental change will be deemed to occur if (i) a change of control transaction occurs in which substantially all of the Company's common stock is exchanged either for consideration other than common stock that is listed on a U.S. national securities exchange or is exchanged for consideration other than common stock that is approved for quotation on a U.S. system of automated dissemination of quotations of securities or (ii) the Company's common stock is neither listed for trading on a U.S. national securities exchange nor approved for listing on any U.S. system of automated dissemination of quotations of securities prices.

Before May 10, 2010, the Company may not redeem the New Notes. On or after May 10, 2010, the Company may redeem any or all of the New Notes at 100% of the principal amount, plus accrued and unpaid interest. In addition, the Company may automatically convert some or all of the New Notes on or prior to the maturity date if the closing price of its common shares has exceeded 130% of the conversion price then in effect for at least 20 trading days during any consecutive 30 trading day period ending within five trading days prior to the notice of auto-conversion (the auto-conversion feature). If a holder elects to voluntarily convert their New Notes or the Company elects to automatically convert some or all of the New Notes on or prior to May 10, 2010, the Company will pay additional interest to holders of New Notes being converted. This additional interest will be equal to the amount of interest that would have been payable on the New Notes from the last day interest was paid on the New Notes, through and including May 10, 2010. Additional interest, if any, will be paid in cash or in common shares of the Company, at the Company's option. If the Company pays additional interest upon a voluntary conversion with its common shares, such shares will be valued at the conversion price that is in effect at that time. If the Company pays additional interest upon an automatic conversion with its common shares, such shares will be valued at 90% of the automatic conversion price that is in effect at that time.

The additional interest payment described above, which may be issued upon conversion, is considered an embedded derivative under SFAS No. 133 and requires bifurcation from the host debt. The Company also considered the provisions of EITF No. 05-2, and concluded that this is not conventional convertible debt.

In accordance with SFAS No. 133, the Company has separately accounted for the additional interest payment feature of the New Notes as an embedded derivative instrument, which is measured at fair value and classified on the accompanying consolidated balance sheets as other long term liabilities. Changes in the fair value of the embedded derivative are recognized in earnings. The derivative liability is revalued quarterly and changes in the fair value through either the date the additional interest payment provisions expire, at which the liability will be zero, or the date at which the additional interest payment provision is triggered, are recorded as other expense or income. For the purpose of accounting for the New Notes issued in the exchange offer, the fair value of the embedded derivative upon issuance was subtracted from the carrying value of the debt and reflected as a debt discount. The debt discount is amortized as interest expense using the effective interest method through the date the notes are scheduled to mature.

**Table of Contents**

Convertible debt upon the exchange and new offering on May 1, 2007 consisted of the following (in thousands):

3.50% Convertible senior notes	\$ 225,692
Discount on convertible notes	(50,781)
Embedded derivative	(3,077)
Total	\$ 171,834

The additional New Notes generated gross proceeds of \$46,500,000. Debt issuance costs, related to the New Notes, of approximately \$6,057,000 are being amortized to interest expense, on a straight-line basis over the 48 month period to maturity of the notes. As of March 31, 2008, the fair value of the derivative is approximately \$153,000 which reflects a change in the fair value of approximately \$130,000 which is included as loss on derivative in the accompanying consolidated statements of operations.

For the three-month period ended March 31, 2008, the Company incurred approximately \$2,149,000 in interest expense on its convertible debt, which is payable on a semi-annual basis. Additionally, the Company amortized approximately \$3,095,000 as non-cash interest expense related to the accretion of the bond discount and approximately \$389,000 in new debt issuance costs.

**(b) Other Financial Arrangements**

To finance the acquisition of ANTARA in August 2006, the Company, together with its wholly-owned subsidiary Guardian II Acquisition Corporation (Guardian II) (the entity which holds all of the ANTARA assets), entered into several financing agreements with Paul Royalty Fund Holdings II, LP, an affiliate of Paul Capital Partners, or Paul Capital, including the Revenue Interests Assignment Agreement, the Note Purchase Agreement and the Common Stock and Warrant Purchase Agreement, in consideration for an aggregate amount of \$70 million.

*Revenue Interests Assignment Agreement*

The Company and Guardian II entered into the Revenue Interests Assignment Agreement (the Revenue Agreement), pursuant to which the Company sold to Paul Capital the right to receive specified royalties on Oscient's net sales in the United States (and the net sales of its affiliates and licensees) of FACTIVE tablets and Guardian II sold to Paul Capital the right to receive specified royalties on Guardian II's net sales in the United States (and the net sales of its affiliates and licensees) of ANTARA capsules, in each case until December 31, 2016. The royalty payable to Paul Capital on net sales of ANTARA and FACTIVE starts each fiscal year as a high single-digit royalty rate and declines to a low single-digit royalty rate based on achievement of annual specified sales thresholds in each fiscal year. Once the cumulative royalty payments to Paul Capital exceed \$100 million, the royalties become nominal.

In connection with the Revenue Agreement, the Company recorded a liability, referred to as the revenue interest liability, of approximately \$40,000,000 in accordance with EITF No. 88-18, Sales of Future Revenues (EITF No. 88-18). The Company imputes interest expense associated with this liability using the effective interest rate method and has recorded a corresponding accrued interest liability. The effective interest rate is calculated based on the rate that would enable the debt to be repaid in full over the life of the arrangement. The interest rate on this liability may vary during the term of the agreement depending on a number of factors, including the level of ANTARA and FACTIVE sales. Payments made to Paul Capital as a result of ANTARA and FACTIVE sales levels will reduce the accrued interest liability and the principal amount of the revenue interest liability. The Company currently estimates that the imputed interest rate associated with this liability will be approximately 19.97%. The Company recorded approximately \$1,908,000 in interest expense related to this agreement in the three-month period ended March 31, 2008. Through March 31, 2008, there have been no principal payments made to Paul Capital as a result of ANTARA or FACTIVE sales.

In the event of (i) a change of control of Oscient or Guardian II, (ii) a bankruptcy of Oscient or Guardian II, (iii) a transfer by Oscient or any of its subsidiaries of substantially all of either ANTARA or FACTIVE, (iv) subject to a cure period, breach of certain material covenants and representations in the Revenue Agreement and (v) in the event the sale of ANTARA is suspended due to a court issued injunction or the Company elects to suspend sales of ANTARA, in each case as a result of a lawsuit by certain third parties (each a Put Event), Paul Capital has the right to require the Company and Guardian II to repurchase from Paul Capital its royalty interest at a price in cash which equals the greater of (a) a specified multiple of cumulative payments made by Paul Capital under the Revenue Agreement less the cumulative royalties previously made to Paul Capital; or (b) the amount which will provide Paul Capital, when taken together with the royalties previously paid, a specified rate of return (the Put/Call Price). Upon a bankruptcy event, the Company and Guardian II are automatically required to repurchase the Paul Capital royalty interest at the Put/Call Price. In the event of a change of control of Oscient, the Company has the right to repurchase the Paul Capital

royalty interest for an amount equal to the Put/Call

**Table of Contents**

Price. The Company has determined that Paul Capital's put option and the Company's call option meet the criteria to be considered an embedded derivative and should be accounted for as such. The Company initially recorded a net liability of \$1,005,000 related to the put/call option to reflect its estimated fair value as of the date of the agreement, in accordance with SFAS No. 133. This liability is revalued on a quarterly basis to reflect any changes in the fair value and any gain or loss resulting from the revaluation is recorded in earnings. As of March 31, 2008, the fair value of the derivative is approximately \$944,000 which reflects a change in the fair value of approximately \$42,000 which has been recorded as a gain on derivative in the accompanying consolidated statements of operations.

During the first two fiscal years immediately following the fiscal year in which combined annual net sales of ANTARA and FACTIVE are equal to or greater than \$125 million, the Company and Guardian II have the right, but not the obligation, to reduce the royalty percentages due under the Revenue Agreement to Paul Capital by fifty percent (50%) by paying Paul Capital a price in cash which will provide Paul Capital, when taken together with the royalties previously paid, a specified rate of return. During the first two fiscal years immediately following the fiscal year in which combined annual net sales of ANTARA and FACTIVE are equal to or greater than \$250 million, the Company and Guardian II have the right, but not the obligation, to repurchase the Paul Capital royalty interest at a price in cash which will provide Paul Capital, when taken together with the royalties previously paid, a specified rate of return.

*Note Purchase Agreement*

Guardian II entered into a Note Purchase Agreement (the "Note Purchase Agreement") with Paul Capital pursuant to which Guardian II issued and sold a \$20,000,000 aggregate principal amount of 12% senior secured note (the "Note"), due on the fourth anniversary of the closing date, subject to Guardian II's option to extend the maturity to the sixth anniversary of the closing date, provided (i) there are no defaults under the Note at the time, and (ii) the Company issues to Paul Capital, at the time of the exercise of such option, a warrant for such number of shares of common stock equal to 10% of the principal balance plus accrued interest divided by \$6.94, with an exercise price of \$6.94 per share. If the Company exercises such option, the number of shares subject to the warrant issuable to Paul Capital would be between 288,018 shares and 367,529 shares, depending upon the amount, if any, of the interest payable on the Note the Company elects to have added to the principal of the Note rather than paid in cash as described below.

Interest is payable semi-annually in arrears on the last day of each of March and September. Guardian II has the option to pay interest in cash or to have 50% of the interest paid in cash and 50% of the interest added to principal. In the event of a change of control of Oscient or on or after the second anniversary of the closing, the Company may at its option prepay all or any part of the Note at a premium which declines over time. In the event of default, with "event of default" defined as a continuing Put Event under the Revenue Agreement as described in more detail above, the outstanding principal and interest in the Note shall become immediately due and payable. From inception of the Note Purchase Agreement, the Company exercised its option to add interest expense payable to the principal of the Note. As of March 31, 2008, the amount added to the principal was approximately \$2,015,000. This amount is recorded as other long-term liabilities on the accompanying consolidated balance sheets.

Subject to the Revenue Agreement and the Note Purchase Agreement, without the prior written consent of Paul Capital, the Company has agreed not to (i) amend, waive any rights under, or terminate any material license agreements, including the agreements relating to the ANTARA and FACTIVE products, (ii) enter into any new agreement or amend or fail to exercise any of its material rights under existing agreements that would have a material adverse effect on Paul Capital's royalty interest, and (iii) sell any material assets related to ANTARA or FACTIVE.

Pursuant to the terms of the Revenue Agreement and the Note Purchase Agreement, Guardian II and Paul Capital entered into a Security Agreement (the "Security Agreement") under which Guardian II granted to Paul Capital a security interest in and to substantially all assets owned by Guardian II (including rights to the ANTARA products) in order to secure its performance under each of the Revenue Agreement, the Note Purchase Agreement and the Note. To the extent the indebtedness under certain of its pre-existing debt obligations is refinanced or replaced and such replacement or refinancing indebtedness is secured, the Company has agreed to equally and ratably secure its obligations under the Revenue Agreement.

*Common Stock and Warrant Purchase Agreement*

As part of the financing, the Company and Paul Capital also entered into a Common Stock and Warrant Purchase Agreement (the "Stock and Warrant Purchase Agreement"), pursuant to which, in exchange for \$10 million, the Company sold to Paul Capital 1,388,889 shares (the "Shares") of the Common Stock, at a price of \$7.20 per share (the "Private Placement") and issued Paul Capital a warrant (the "Warrant") to purchase 288,018 shares of Common Stock (the "Warrant Shares") at an exercise price of \$6.94 per share. The Warrant is exercisable for seven years from the date of closing. The Warrant contains a net share settlement feature and penalties if the Company does not deliver the applicable amount of



**Table of Contents**

Warrant Shares within three trading days of exercise of a Warrant by Paul Capital. The Warrant also contains provisions providing that, at Paul Capital's election, the Company must repurchase the Warrant from Paul Capital upon a sale of the Company in which the consideration for such sale is solely cash. The warrant has not been exercised as of March 31, 2008. The Company agreed, pursuant to the Stock and Warrant Purchase Agreement, to elect one person designated by Paul Capital to its Board of Directors following the closing and to continue to nominate one person designated by Paul Capital for election to its Board of Directors by its shareholders. The director designated by Paul Capital shall resign and the Company shall no longer be required to nominate a director designated by Paul Capital upon the later of the following events: (1) if Paul Capital ceases to own at least five percent of the Company's Common Stock or securities convertible into its Common Stock; (2) if the Company owes Paul Capital less than \$5,000,000 under the Note pursuant to the Note Purchase Agreement; (3) the cumulative payments to Paul Capital made by the Company under the terms of the Revenue Agreement first exceed 250% of the consideration paid to the Company by Paul Capital; or (4) if the amounts due by the Company pursuant to the Revenue Agreement cease to be due. If at any time Paul Capital's designee is not elected to the Company's Board of Directors, Paul Capital's designee will have a right to participate in all meetings of the Company's Board of Directors in a nonvoting observer capacity.

The following table presents future maturities of debt (in thousands):

<b>Year-Ending December 31,</b>	
2008	\$ 29
2009	13,338
2010	20,038
2011	183,403
2012	
Thereafter	40,589
<b>Total</b>	<b>\$ 257,397</b>

**(8) Supply Agreement for ANTARA**

In accordance with the acquisition of ANTARA in August of 2006, the Company was assigned rights to and assumed certain obligations under an exclusive license to the rights to ANTARA licensed from Ethypharm S.A. In order to maintain the exclusivity of these rights, the Company must achieve minimum annual sales in the United States until February 2012 or pay amounts to Ethypharm to compensate for any shortfall. During the term of the agreement, the Company is obligated to pay Ethypharm a royalty on sales of ANTARA in the U.S. including a royalty on other fenofibrate monotherapy products in formulations and dosage forms that may be substantially similar or identical to ANTARA developed by the Company. The license term expires in February 2020 and, absent notice of termination by either party, automatically renews for additional two year periods. Under the terms of the agreement, at the Company's option, Ethypharm is obligated to either manufacture and deliver to the Company finished fenofibrate product or deliver API to the Company for encapsulation and packaging. Ethypharm also has a right of first refusal on any divestiture of the ANTARA rights by the Company. Additional Company obligations under the Ethypharm agreement include funding a portion of the active pharmaceutical ingredient safety stock that Ethypharm is required to maintain.

**(9) Supply Agreement for FACTIVE**

The Company licenses from LG Life Sciences the right to develop and commercialize gemifloxacin (FACTIVE) tablets, a novel fluoroquinolone antibiotic, in North America, France, Germany, the United Kingdom, Luxembourg, Ireland, Italy, Spain, Portugal, Belgium, the Netherlands, Austria, Greece, Sweden, Denmark, Finland, Norway, Iceland, Switzerland, Andorra, Monaco, San Marino, Vatican City, Poland, Czech Republic, Slovakia, Slovenia, Hungary, Estonia, Latvia, Lithuania, Liechtenstein, Malta, Cyprus, Romania, Bulgaria, Croatia, Serbia and Montenegro, Bosnia and Herzegovina, Albania and the Former Yugoslav Republic of Macedonia. The term of the agreement with respect to each country extends at least through the life of the patents covering gemifloxacin in such country. In the United States, the last of the issued patents for composition of matter expires in 2018. The patent term could extend further in countries outside of the U.S. depending upon several factors, including whether the Company obtains patent extensions and the timing of its commercial sale of the product in a particular country.

Under the terms of the agreement, LG Life Sciences has agreed to supply and the Company is obligated to purchase from LG Life Sciences all of its anticipated commercial requirements for the FACTIVE active pharmaceutical ingredient (API). LG Life Sciences currently supplies the FACTIVE API from its manufacturing facility in South Korea.





**Table of Contents**

The agreement with LG Life Sciences also requires the Company to achieve minimum gross sales level of \$30 million from its licensed territories over a 12-month period of time starting in approximately the third quarter of 2007 to the third quarter of 2008, which if not met, LG Life Sciences could elect to terminate the agreement and have the technology be returned to LG Life Sciences. Under this agreement, the Company is responsible, at its expense and through consultation with LG Life Sciences, for the clinical and commercial development of gemifloxacin in the countries covered by the license, including conducting of clinical trials, filing drug approval applications with the FDA and other applicable regulatory authorities and marketing, distributing and selling of gemifloxacin in its territory.

The Company is obligated to pay a royalty on sales of FACTIVE in North America and the territories covered by the license in Europe. These royalty obligations expire with respect to each country covered by the agreement on the later of (i) the expiration of the patents covering FACTIVE in such country or (ii) the expiration of data exclusivity in Mexico, Canada or the European Union respectively, or 2014 in the U.S. The Company is also obligated to make aggregate milestone payments of up to \$40 million to LG Life Sciences upon achievement of additional regulatory approvals and sales thresholds. On December 27, 2006, the Company amended its agreement with LG Life Sciences to reduce future royalties payable to LG Life Sciences for sales of FACTIVE tablets in Europe and to provide for a reduction in the supply price for the API for FACTIVE for product to be sold in Europe. In lieu of milestone payments previously agreed to by the parties, this amendment also requires the Company to pay LG Life Sciences a portion of any milestone or license fee payments the Company receives from its European partner.

**ITEM 2: MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*Forward-Looking Statements*

Certain statements contained herein related to future operating losses and our potential for profitability, the sufficiency of our cash resources, future revenues and sales of ANTARA and FACTIVE, our discount and rebate programs for ANTARA and FACTIVE, possible partnering or other strategic opportunities for the continued development of Ramoplanin, potential marketing approval of FACTIVE in Europe, the possibility of acquiring a third product, as well as other statements related to the progress and timing of product development, present or future licensing, collaborative or financing arrangements or that otherwise relate to future periods, are forward-looking statements as defined by the Private Securities Litigation Reform Act of 1995. These statements represent, among other things, the expectations, beliefs, plans and objectives of management and/or assumptions underlying or judgments concerning the future financial performance and other matters discussed in this document. The words may, will, should, plan, believe, estimate, intend, anticipate, project, and expect and similar expressions identify forward-looking statements. All forward-looking statements involve certain risks, estimates, assumptions, and uncertainties with respect to future revenues, cash flows, expenses and the cost of capital, among other things.

Some of the important risk factors that could cause our actual results to differ materially from those expressed in our forward-looking statements are included under the heading Risk Factors in this Form 10-Q. We encourage you to read these risks carefully. We caution investors not to place significant reliance on the forward-looking statements contained in this report. These statements, like all statements in this report, speak only as of the date of this report (unless another date is indicated) and we undertake no obligation to update or revise forward-looking statements.

**Overview**

Oscient Pharmaceuticals Corporation ( we , us , or the Company ) is a commercial-stage pharmaceutical company marketing Food and Drug Administration (FDA)-approved products in the United States. Our strategy is to grow the sales of our existing products and to gain access to new products via transactions, including acquisition, in-licensing and co-promotion. We have developed a commercial infrastructure, including a national sales force calling on targeted primary care physicians, cardiologists, endocrinologists and pulmonologists in the United States.

We currently market two products: ANTARA® (fenofibrate) capsules, a cardiovascular product, and FACTIVE® (gemifloxacin mesylate) tablets, a fluoroquinolone antibiotic. ANTARA is approved by the FDA to treat hypercholesterolemia (high blood cholesterol) and hypertriglyceridemia (high triglycerides) in combination with a healthy diet. We license the rights to ANTARA from Ethypharm S.A. of France (Ethypharm) and began promoting ANTARA in late August 2006. FACTIVE is indicated for the treatment of community-acquired pneumonia of mild to moderate severity, or CAP, and acute bacterial exacerbations of chronic bronchitis, or AECB. We license the rights to gemifloxacin, the active ingredient in FACTIVE tablets, from LG Life Sciences of the Republic of Korea (LG Life Sciences) and launched FACTIVE in the U.S. market in September 2004.

Additionally, we have a novel, late-stage antibiotic candidate, Ramoplanin, for the treatment of *Clostridium difficile*-associated disease, or CDAD. We have made the strategic decision to concentrate our financial resources on building our revenues for products promoted to community-based physicians in the United States and are currently seeking to out-license, co-develop or sell the rights to Ramoplanin to a

partner.

---

## **Table of Contents**

We have incurred significant operating losses in the past. As of March 31, 2008, we had an accumulated deficit of approximately \$467.2 million. We expect to incur additional operating losses until we achieve a level of product sales sufficient to cover our operating and other expenses.

### **ANTARA**

ANTARA is a once-daily formulation of fenofibrate approved for use in combination with a diet restricted in saturated fat and cholesterol to reduce elevated LDL-C ( bad cholesterol), triglyceride and apolipoprotein B (free floating fats in the blood) levels and to increase HDL-C ( good cholesterol) in adult patients with high cholesterol or an abnormal concentration of lipids in the blood. Fenofibrate products work primarily to lower triglycerides and increase HDL-C, which makes the drug an attractive alternative for those patients whose LDL-C is well controlled. ANTARA received FDA approval in November 2004. We began marketing ANTARA in 43 mg and 130 mg doses in August 2006.

On August 18, 2006, we acquired rights to ANTARA in the United States from Reliant Pharmaceuticals Inc. (Reliant) for \$78 million plus approximately \$4.3 million for ANTARA inventory, excluding estimated transaction costs. Under the terms of our acquisition of ANTARA, we assumed certain of Reliant's liabilities related to ANTARA, including obligations to make certain royalty and milestone payments on sales of ANTARA. Under the terms of one of the licenses we assumed related to ANTARA, we are obligated to make certain royalty payments on sales of ANTARA, which royalty payments are subject to a low single digit increase in the event of a change in control of the Company. The license also limits our ability to co-promote ANTARA with companies other than contract sales organizations or similar companies. Under the terms of our acquisition of ANTARA we were also assigned rights to an exclusive license from Ethypharm S.A. (Ethypharm). Pursuant to the Ethypharm license, in order to maintain the exclusivity of our rights, we must achieve minimum annual sales in the United States until February 2012 or alternatively compensate Ethypharm for any shortfall. As of March 31, 2008, we recorded approximately \$605,000 related to the minimum royalty obligation to Ethypharm. During the term of the agreement with Ethypharm, we are obligated to pay a royalty on net sales of ANTARA in the U.S., including a royalty on other fenofibrate monotherapy products in formulations and dosage forms that may be substantially similar or identical to ANTARA developed by us. The license term expires in February 2020 and, absent notice of termination by either party, automatically renews for consecutive periods of two (2) years each. Under the terms of the agreement, at our option, Ethypharm is obligated to either manufacture and deliver to us finished fenofibrate product or deliver active pharmaceutical ingredient (API) to us for encapsulation and packaging. Ethypharm also has a right of first refusal on any divestiture of the ANTARA rights by us. Additional Oscient obligations under the Ethypharm agreement include funding a portion of the active pharmaceutical ingredient safety stock that Ethypharm is required to maintain.

Pursuant to the terms of our acquisition of ANTARA from Reliant, we also acquired the New Drug Application, or NDA and the Investigational New Drug application, or IND, covering the ANTARA products in the United States, clinical data, inventory, the ANTARA<sup>®</sup> trademark in the United States and certain related contracts and licenses covering intellectual property rights related to the ANTARA products. We also assumed certain of Reliant's liabilities relating to the ANTARA products.

We are not required to pay Reliant a royalty on the sale of the ANTARA products; however, we are required to pay a low single-digit royalty to Reliant for a specified time period on net sales of any line extensions and improvements to the ANTARA products that we develop, which include any product containing fenofibrate as its API. We currently do not pay royalties to Reliant. We also agreed that we would not, at any time prior to August 2016, develop or sell any product in the United States that is a combination of fenofibrate and an omega-3 compound without the prior written consent of Reliant. On December 19, 2007, Reliant was acquired by GlaxoSmithKline.

ANTARA capsules are covered by a U.S. patent relating to formulations containing fenofibrate and methods of preparing the same that extend through August 2020. In addition, Ethypharm has filed additional patent applications which relate to the formulation and we were assigned a patent application which was filed by Reliant relating to methods of treatment. If issued, we believe these patents may provide ANTARA additional patent protection.

### **FACTIVE**

#### *Overview*

FACTIVE was approved by the FDA in 2003 for the treatment of community-acquired pneumonia of mild to moderate severity, or CAP, and acute bacterial exacerbations of chronic bronchitis, or AECB.

---

**Table of Contents**

We license from LG Life Sciences the right to develop and commercialize FACTIVE (gemifloxacin) tablets, a fluoroquinolone antibiotic, in North America, France, Germany, the United Kingdom, Luxembourg, Ireland, Italy, Spain, Portugal, Belgium, the Netherlands, Austria, Greece, Sweden, Denmark, Finland, Norway, Iceland, Switzerland, Andorra, Monaco, San Marino, Vatican City, Poland, Czech Republic, Slovakia, Slovenia, Hungary, Estonia, Latvia, Lithuania, Liechtenstein, Malta, Cyprus, Romania, Bulgaria, Croatia, Serbia and Montenegro, Bosnia and Herzegovina, Albania and the Former Yugoslav Republic of Macedonia. The term of the agreement with respect to each country extends at least through the life of the patents covering gemifloxacin in such country. In the United States, the last of the issued patents for composition of matter expires in 2018. The patent term could extend further in countries outside of the U.S. depending upon several factors, including whether we obtain patent extensions and the timing of our commercial sale of the product in a particular country.

Under the terms of the agreement, LG Life Sciences has agreed to supply and we are obligated to purchase from LG Life Sciences all of our anticipated commercial requirements for the FACTIVE API. LG Life Sciences currently supplies the FACTIVE API from its manufacturing facility in South Korea.

The agreement with LG Life Sciences also requires that we achieve a minimum gross sales level of \$30 million from our licensed territories over a 12-month period of time starting in approximately the third quarter of 2007 to the third quarter of 2008 which, if not met, LG Life Sciences could elect to terminate the agreement and have the technology be returned to LG Life Sciences. Under this agreement, we are responsible, at our expense and through consultation with LG Life Sciences, for the clinical and commercial development of gemifloxacin in the countries covered by the license, including conducting clinical trials, filing drug approval applications with the FDA and other applicable regulatory authorities and marketing, distributing and selling of gemifloxacin in our territory.

We are obligated to pay a royalty on sales of FACTIVE in North America and the territories covered by the license in Europe. These royalty obligations expire with respect to each country covered by the agreement on the later of (i) the expiration of the patents covering FACTIVE in such country or (ii) the expiration of data exclusivity in Mexico, Canada or the European Union respectively, or 2014 in the U.S. We are also obligated to make aggregate milestone payments of up to \$40 million to LG Life Sciences (including milestone payments required by the amendments described below) upon achievement of additional regulatory approvals and sales thresholds.

On March 31, 2005, we amended our license and option agreement with LG Life Sciences which included a payment and additional milestones as well as a reduction of future royalties payable to LG Life Sciences at certain FACTIVE revenue levels in territories covered by the agreement. We further amended our agreement with LG Life Sciences on February 3, 2006, pursuant to which LG Life Sciences agreed to a reduction of future royalties payable for sales of FACTIVE tablets in Mexico and Canada and the termination of LG Life Sciences' co-promotion rights in these countries. The modified agreement also calls for additional milestone payments to be made to LG Life Sciences upon consummation of sublicense agreements in Mexico and Canada (which payments were made to LG Life Science in February 2006 and August 2006, respectively) as well as upon receipt of regulatory approval of FACTIVE in each of such countries. Additionally, on December 27, 2006, we amended our agreement with LG Life Sciences to reduce future royalties payable to LG Life Sciences for sales of FACTIVE tablets in Europe and to provide for a reduction in the supply price for the API for FACTIVE for product to be sold in Europe. In lieu of milestone payments previously agreed to by the parties, this amendment also requires us to pay LG Life Sciences a portion of any milestone or license fee payments we receive from our European partner.

*Commercialization and Development*

With respect to additional development initiatives, we completed a clinical trial designed to demonstrate that a five-day course of FACTIVE for the treatment of mild to moderate CAP is as effective as the previously approved seven-day course of treatment. On September 21, 2006, we received an approvable letter from the FDA for the supplemental New Drug Application (sNDA) seeking approval for the five-day treatment of CAP with FACTIVE tablets. In accordance with the letter, we provided clarification and additional interpretation regarding certain data included in the application to assist the FDA in its evaluation. On May 1, 2007, the FDA approved FACTIVE for the five-day treatment of CAP.

As part of the FACTIVE development program, several studies relating to acute bacterial sinusitis, or ABS, were completed, and, in November 2005, we filed an sNDA for ABS. In September 2006, the FDA's Anti-Infective Drugs Advisory Committee voted not to recommend approval of this sNDA. In November 2006, we voluntarily withdrew our sNDA seeking approval of the ABS indication.

On February 6, 2006, we entered into a Sublicensing and Distribution Agreement with Pfizer, S.A. de C.V. (Pfizer Mexico), pursuant to which we sublicensed our rights to sell FACTIVE tablets in Mexico to Pfizer Mexico. In exchange for

---

**Table of Contents**

those rights, Pfizer Mexico has paid us an up-front payment and has agreed to pay us milestone payments upon obtaining certain regulatory approvals and sales goals as well as royalties on future sales. The up-front payment is being recognized as revenue over the term of our continuing obligations under the agreement. These royalty rates are subject to reduction upon expiration of certain patents in Mexico for FACTIVE or if a generic form of gemifloxacin has a material impact on Pfizer Mexico's sales volumes in Mexico. Pfizer Mexico is obligated to exclusively purchase from us, and we must exclusively supply, all API for FACTIVE. The agreement with Pfizer Mexico may be terminated by either party upon the occurrence of certain termination events, including Pfizer Mexico's right to terminate at any time after the first anniversary of launch of FACTIVE tablets in Mexico upon nine months prior written notice. Upon termination, Pfizer Mexico is obligated to assign any and all rights to regulatory approvals in Mexico to us or our designee. Pfizer Mexico is currently marketing FACTIVE-5 in Mexico for the treatment of CAP, AECB and ABS.

On August 9, 2006, we granted the commercialization rights to FACTIVE tablets in Canada to Abbott Laboratories, Ltd. (Abbott Canada), the Canadian affiliate of Abbott. In exchange for those rights, Abbott Canada agreed to a transfer price on product purchases and to make certain payments to us upon achievement of certain regulatory and sales milestones. FACTIVE is currently approved in Canada for the five-day treatment of AECB. We subsequently amended the agreement on January 31, 2008 whereby Abbott Canada's development and commercialization obligations were substantially reduced. In accordance with the terms of the amendment, Abbott Canada will continue to maintain FACTIVE tablets in its current product price list and it will continue to pay us a transfer price on FACTIVE tablets purchases. Abbott Canada is not required to pursue the CAP and ABS indications. Additionally, the amendment provides that we can terminate the agreement at any time with prior notice to Abbott Canada and Abbott Canada can terminate with prior notice to us after November 30, 2008.

We entered into a License, Supply and Marketing Agreement with Menarini International Operation Luxembourg S.A. (Menarini), a wholly-owned subsidiary of Menarini Industrie Farmaceutiche Riunite S.r.l. dated December 28, 2006, whereby we sublicensed our rights to sell FACTIVE tablets in the European Union to Menarini. Under the terms of our agreement with Menarini, Menarini is responsible for obtaining regulatory approval for FACTIVE in the European Union. Oscient has agreed to reimburse Menarini for expenses associated with such regulatory development up to an agreed limit. Menarini has paid us an up-front payment and agreed to pay us milestone payments upon obtaining certain regulatory and reimbursement approvals and upon achieving certain annual net sales goals, which could total up to \$23 million if all the milestones are achieved. Menarini will pay us a transfer price on purchases of the active pharmaceutical ingredient, or API, for FACTIVE, which is determined based on a percentage of quarterly sales of FACTIVE by Menarini in Europe. Menarini is also obligated to exclusively purchase from us, and we must exclusively supply, all API for FACTIVE to be sold in Europe for the earlier of (i) the expiration of the life of certain patents covering the product or (ii) expiration of data exclusivity. Our agreement with Menarini may be terminated by either party upon the occurrence of certain termination events, including Menarini's right to terminate if the European regulatory authorities do not recommend approval of FACTIVE at various stages of the approval process with a package insert, or label, that meets certain requirements as to the safety, dosing and indications for which FACTIVE may be prescribed. Menarini may also terminate the agreement if it does not receive approval for reimbursement from European Union member countries that is above a certain minimum price per tablet. Upon termination, Menarini is obligated to assign any and all rights to regulatory approvals in the European Union to Oscient or its designee. Menarini recently submitted a regulatory filing seeking approval of FACTIVE in Europe for the treatment of community-acquired pneumonia, acute bacterial exacerbations of chronic bronchitis and acute bacterial sinusitis.

**Research and Development Programs****FACTIVE**

As a condition to the approval to sell FACTIVE tablets, the FDA required, as a post-marketing study commitment, that we conduct a prospective, randomized study examining the activity of FACTIVE tablets (5,000 patients) versus an active comparator (2,500 patients) in patients with acute bacterial exacerbations of chronic bronchitis and community-acquired pneumonia of mild to moderate severity. This study included patients of different ethnicities to gain safety information in populations not substantially represented in the existing clinical trial program. This Phase IV trial was initiated in the fall of 2004 and was completed in January 2007. The final report of the utilization study is scheduled for submission to the FDA in the first half of 2008. In the future, we need only to provide the FDA with annual reports containing safety information.

Additionally, in April 2005, we completed a Phase III trial examining the potential use of FACTIVE tablets for the five-day treatment of mild to moderate CAP. Based on the results of this study, in November 2005 we submitted an sNDA to the FDA for approval to promote the five-day treatment of FACTIVE tablets for this indication. On September 21, 2006, we received an approvable letter from the FDA for the sNDA seeking approval for the five-day treatment of CAP with FACTIVE tablets. In accordance with the letter, we provided clarification and additional interpretation regarding certain data included in the application to assist the FDA in its evaluation. On May 1, 2007, the FDA approved FACTIVE for the five-day treatment of CAP.



---

## **Table of Contents**

### **Ramoplanin**

We have a novel, late-stage investigational antibiotic candidate, Ramoplanin, under investigation for the treatment of *Clostridium difficile*-associated disease, or CDAD. In October 2001, we in-licensed Ramoplanin from Vicuron Pharmaceuticals Inc. (Vicuron), now a wholly-owned subsidiary of Pfizer Inc., and on February 3, 2006, acquired worldwide rights from Vicuron, assuming full rights to the manufacturing, development and commercialization of Ramoplanin.

We agreed with the FDA to a Special Protocol Assessment (SPA) regarding the specific components of a Phase III program that, if completed successfully, would support regulatory approval for the indication. With the acquisition of ANTARA, we have made the strategic decision to concentrate our financial resources on building its revenues for products promoted to community-based physicians in the United States and are currently seeking to out-license, co-develop or sell our rights to Ramoplanin to a partner.

### **Critical Accounting Policies & Estimates**

We have identified the policies below as critical to our business operations and the understanding of our results of operations. The impact and any associated risks related to these policies on our business operations is discussed throughout Management's Discussion and Analysis of Financial Condition and Results of Operations where such policies affect our reported and expected financial results. For a detailed discussion on the application of these and other accounting policies, see Note 2 in the Notes to the Consolidated Financial Statements for the year ended December 31, 2007 which are included in our Annual Report on Form 10-K. Our preparation of our financial statements requires us to make estimates and assumptions that affect the reported amount of assets and liabilities, the disclosure of contingent assets and liabilities at the date of our consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Our critical accounting policies include the following:

#### **Revenue Recognition**

Our principal source of revenue is the sale of ANTARA capsules and FACTIVE tablets. ANTARA revenue results are anticipated to be steady throughout our fiscal year. We expect demand for FACTIVE to be highest from December to March as the incidence of respiratory tract infections, including CAP and AECB, tends to increase during the winter months. In addition, fluctuations in the severity of the annual respiratory tract infection season may cause our product sales to vary from year to year. Due to these seasonal fluctuations in demand for FACTIVE, our results in any particular quarter may not be indicative of the results for any other quarter or for the entire year.

#### **Product Sales**

We follow the provisions of Staff Accounting Bulletin (SAB) No. 104, Revenue Recognition (a replacement of SAB 101) (SAB No. 104) and recognize revenue from product sales upon delivery of product to wholesalers, when persuasive evidence of an arrangement exists, the fee is fixed or determinable, title to product and associated risk of loss has passed to the wholesaler and collectability of the related receivable is reasonably assured. All revenues from product sales are recorded net of applicable allowances for sales returns, rebates, special promotional programs, and discounts. For arrangements where the risk of loss has not passed to wholesalers or pharmacies, we defer the recognition of revenue by recording deferred revenue until such time that risk of loss has passed. The cost of ANTARA and FACTIVE associated with amounts recorded as deferred revenue is recorded in inventory until such time as risk of loss has passed.

#### **Other Revenues**

Other revenues primarily consist of sublicensing revenues related to FACTIVE. We recognize revenue in accordance with SAB No. 104 and Emerging Issues Task Force (EITF) Issue No. 00-21, Revenue Arrangements with Multiple Deliverables (EITF No. 00-21). In accordance with EITF No. 00-21, the up-front license payments related to the various sublicense agreements will be recognized as revenue over the term of our continuing obligations under the arrangements which range from 18 months to 33 months. Substantive milestones achieved are recognized as revenue when earned and when payment is reasonably assured, if we have completed our remaining obligations under the arrangement. If we have further obligations, milestone payments are recognized as revenue if we have sufficient evidence of fair value for our remaining obligations otherwise the milestone payment is recognized as revenue over the remaining performance period. Incremental direct costs associated with sublicense agreements are expensed in the period in which the expense is incurred.

#### **Sales Rebates, Discounts and Incentives**

In the U.S., we sell ANTARA and FACTIVE to pharmaceutical wholesalers for further distribution through pharmacies to the ultimate consumers of the product. When we deliver our product, we reduce the amount of gross revenue recognized from such product sales based



## Edgar Filing: OSCIENT PHARMACEUTICALS CORP - Form 10-Q

primarily on estimates of four categories of discounts and allowances that suggest that all or part of the revenue should not be recognized at the time of the delivery product returns, cash discounts, rebates, and special promotional programs.

---

**Table of Contents***Product Returns*

Factors that are considered in our estimate of future ANTARA and FACTIVE product returns include an analysis of the amount of product in the wholesaler and pharmacy channel, review of consumer consumption data as reported by external information management companies, actual and historical return rates for expired lots, the remaining time to expiration of our product, and our forecast of future sales of our product. Consistent with industry practice, we offer contractual return rights that allow our customers to return product within six months prior to, and twelve months subsequent to, the expiration date of our product. ANTARA capsules and FACTIVE tablets each have a 36-month expiration period from the date of manufacturing. As of March 31, 2008 and December 31, 2007, our product return reserve was approximately \$3,600,000 and \$3,169,000, respectively. This reserve is evaluated on a quarterly basis, assessing each of the factors described above, and adjusted accordingly. Based on the factors noted above, we believe our estimate of product returns is reasonable, and changes, if any, from this estimate would not have a material impact to our financial statements.

*Cash Discounts*

Our standard invoice includes a contractual cash 2% discount, net 30 days terms. Based on historical experience, we estimate that most of our customers deduct a 2% discount from their balance. The cash discount reserve is presented as an allowance against trade receivables in the consolidated balance sheets. As of March 31, 2008 and December 31, 2007, the balance of the cash discounts reserve was approximately \$195,000 and \$343,000, respectively.

*Rebates*

The liability for commercial managed care rebates is calculated based on historical and current rebate redemption and utilization rates with respect to each commercial contract. The liability for Medicaid rebates is calculated based on historical and current rebate redemption and utilization rates contractually submitted by each state. As of March 31, 2008 and December 31, 2007, the balance of the accrual for managed care and Medicaid rebates for ANTARA and FACTIVE in total was approximately \$3,319,000 and \$4,263,000, respectively. Considering the estimates made by us, as well as estimates reflected in third party utilization reports that are used in evaluating the required liability balance, we believe our estimates are reasonable.

*Special Promotional Programs*

From time to time, we offer certain promotional incentives to our customers for both ANTARA and FACTIVE and will continue this practice in the future. Such programs include: sample cards to retail consumers, certain product incentives to pharmacy customers, and other sales stocking allowances. We account for these programs in accordance with EITF No. 01-09, Accounting for Consideration Given by a Vendor to a Customer (EITF No. 01-09). Examples of programs utilized to date are as follows:

*Voucher Rebate Programs for ANTARA*

Since acquiring ANTARA in August 2006, we have initiated four voucher rebate programs for ANTARA whereby we offered a point-of-sale rebate to retail consumers. The liabilities we recorded for these voucher rebate programs were estimated based upon the historical rebate redemption rates for similar completed programs by other pharmaceutical companies as reported to us by a third party claims processing organization and actual redemption rates on our similar completed programs. The first program expired on December 31, 2006, the second program expired on September 30, 2007, the third program expires on February 28, 2009 and the fourth program expires on March 31, 2009. As of March 31, 2008 and December 31, 2007, the balance of the liabilities for these voucher programs totaled approximately \$383,000 and \$491,000, respectively.

*Voucher Rebate Programs for FACTIVE*

We periodically initiate voucher rebate programs for FACTIVE whereby we offer point-of-sale rebates to retail consumers. The liabilities we record for these voucher rebate programs are estimated based upon the historical rebate redemption rates for similar completed programs. In April 2007, we initiated a voucher rebate program whereby we offered a point-of-sale rebate to retail consumers. This program expired on December 31, 2007. In October 2007, we initiated another voucher rebated program whereby we offered a point-of-sale rebate to retail consumers. This program expires on April 30, 2008. As of March 31, 2008 and December 31, 2007, the balance of the liabilities for these voucher programs totaled approximately \$1,254,000 and \$1,396,000, respectively.



---

**Table of Contents****Long-Lived Assets**

We follow the provisions of Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS No. 144). Under SFAS No. 144, long-lived assets and identifiable intangible assets with finite lives are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If indicators of impairment exist, recoverability of assets to be held and used is assessed by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. Recoverability measurement and estimating the undiscounted cash flows are each done at the lowest possible level for which there are identifiable assets. If the aggregate undiscounted cash flows are less than the carrying value of the asset, then the resulting impairment charge to be recorded is calculated based on the amount by which the carrying amount of the asset exceeds its fair value. Any write-downs are recorded as permanent reductions in the carrying amount of the asset.

During 2007, events and circumstances, primarily a reduction in projected long term cash flows, indicated that the FACTIVE intangible asset could become impaired. However, at December 31, 2007, our estimate of undiscounted cash flows indicated that such carrying amounts are expected to be recovered and therefore the assets are not impaired. As a result of the reduction of the projected long term cash flows at the end of 2007, we reviewed and updated our cash flow projections as of March 31, 2008, which indicated that the carrying amounts are expected to be recovered and therefore the intangible assets of FACTIVE are not impaired. Nonetheless, it is reasonably possible that the estimate of undiscounted cash flows may change in the near term resulting in the need to write down the intangible asset associated with FACTIVE to fair value. Our estimate of undiscounted cash flows is based upon several significant assumptions including, but not limited to, estimated domestic sales growth, the ability to significantly penetrate international markets and the ability to satisfy our minimum requirements under the agreement with the licensor, LG Life Science.

We also follow the provisions of SFAS No. 142, *Goodwill and Other Intangible Assets*, (SFAS No. 142). Under SFAS No. 142, goodwill and purchased intangible assets with indefinite lives are not amortized but are reviewed periodically for impairment. We perform an annual evaluation of goodwill at the end of each fiscal year to test for impairment or more frequently if events or circumstances indicate that goodwill may be impaired. Because we have a single operating segment, which is our sole reporting unit, we perform this test by comparing the fair value of the entity as measured by the quoted market price of our common stock with our book value, including goodwill, which at present is a deficit. If the fair value exceeds the book value, goodwill is not impaired. If the book value exceeds the fair value, then we would calculate the potential impairment loss by comparing the implied fair value of goodwill with the book value. If the implied fair value of goodwill is less than the book value, then an impairment charge would be recorded.

As of March 31, 2008, we do not believe that any of our long-lived assets, goodwill, and other intangible assets are impaired.

**Stock-Based Compensation**

Effective January 1, 2006, we adopted SFAS No. 123 (Revised 2004), *Share-Based Payment* (SFAS No. 123R) using the modified prospective transition method. SFAS No. 123R requires all share-based payments, including grants of stock options, to be recognized in the income statement as an operating expense, based on their fair values. Under the modified prospective transition method, compensation cost recognized during the twelve months ended December 31, 2006 includes (1) compensation cost for all share-based payments granted prior to, but not vested as of December 31, 2005, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS No. 123) and (2) compensation cost for all share-based payments granted subsequent to December 31, 2005, based on the grant date fair value estimated in accordance with the provisions of SFAS No. 123R. Such amounts have been reduced by our estimate of forfeitures on all unvested awards. Stock-based compensation expense primarily relates to stock options, restricted stock, and stock issued under our employee stock purchase plan.

The fair value of each stock option award is estimated on the grant date using the Black-Scholes-Merton option-pricing model based on the assumptions of volatility, risk-free interest rates, expected life of the option, and dividends (if any). The expected life of the stock options granted was estimated based on the historical exercise patterns over the option lives while considering employee exercise strategy and cancellation behavior. The expected life of options used for the three-month period ended March 31, 2008 ranged from 5.55 to 6.17 years. The expected volatility is determined based on historical volatility data of our common stock from the period of time beginning with our merger with Genesoft in February 2004 and other factors through the month of grant. Our expected volatility for the three-month period ended March 31, 2008 was between 60.86% and 62.07%. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected life assumption. Our risk-free interest rate for the three-month period ended March 31, 2008 was between 3.00% and 3.15%. We have not paid and do not expect to pay any dividends; as a result, our dividend yield is assumed to be 0%.

Our policy is to recognize compensation cost for awards with service conditions and graded vesting using the straight-line method. Additionally, our policy is to issue authorized but previously unissued shares to satisfy share option exercises, the issuance of restricted stock and stock issued under the ESPP. The amount of stock-based compensation recognized during



---

## **Table of Contents**

a period is based on the value of the portion of the awards that are ultimately expected to vest. In addition, the requisite service period is generally equal to the vesting term. SFAS No. 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The term forfeitures is distinct from cancellations or expirations and represents only the unvested portion of the surrendered option. We have applied an annual forfeiture rate of 21.39% to all unvested options as of March 31, 2008. This analysis will be re-evaluated annually and the forfeiture rate will be adjusted as necessary. Ultimately, the actual expense recognized over the vesting period will only be for those shares that vest.

Stock compensation expense recorded in the three-month periods ended March 31, 2008 and 2007 was \$578,000 and \$702,000, respectively. The compensation expense under SFAS No. 123R is recorded in cost of product sales, research and development expense, selling and marketing expense, and general and administrative expense based on the specific allocation of employees receiving the equity awards.

As of March 31, 2008, we estimate there is approximately \$3,435,000 of total unrecognized compensation cost related to unvested share based awards. These costs are expected to be recognized over a weighted average remaining requisite service period of 1.46 years. We expect approximately 822,000 in unvested options to vest at some point in the future. The value of options expected to vest is calculated by applying an estimated forfeiture rate to the unvested options.

### **Recent Accounting Pronouncements**

#### *Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133*

In March 2008, the Financial Accounting Standards Board (FASB) issued FASB Statement No. 161, *Disclosures about Derivative Instruments and Hedging Activities* (SFAS No. 161). SFAS No. 161 requires entities to provide greater transparency about (a) how and why and entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for under SFAS No. 133 and its related interpretations, and (c) how derivative instruments and related hedged items affect an entity's financial position, results of operations, and cash flows. SFAS No. 161 is effective for financial statement issued for fiscal years and interim periods beginning after November 15, 2008. We are currently in the process of studying the impact of this standard on our financial accounting and reporting.

#### *Business Combinations*

In December 2007, the FASB issued Statement No. 141R, *Business Combinations* (SFAS No. 141R). SFAS No. 141R improves consistency and comparability of information about the nature and effect of a business combination by establishing principles and requirements for how an acquirer (a) recognizes and measures in its financial statements the identifiable assets acquired, liabilities assumed and any noncontrolling interest in the acquiree; (b) recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase; and (c) determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. SFAS No. 141R applies prospectively to all business combination transactions for which the acquisition date is on or after January 1, 2009. The impact of our adoption of SFAS No. 141R will depend upon the nature and terms of business combinations, if any, that we consummate on or after January 1, 2009.

#### *Accounting for Collaborative Arrangements*

In November 2007, EITF issued EITF Issue No. 07-01 *Accounting for Collaborative Arrangements* (EITF No. 07-01). EITF No. 07-01 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable generally accepted accounting principles (GAAP) or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. Further, EITF No. 07-01 clarified that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to Issue No. 01-9, *Accounting for Consideration Given by a Vendor to a Customer* EITF No. 07-01 is effective for fiscal years beginning after December 15, 2008. We have not yet completed our evaluation of EITF No. 07-01, but do not currently believe that it will have a material impact on the results of operations, financial position or cash flows.

### **Results of operations**

#### *Three-Month Period Ended March 31, 2008 and March 31, 2007*

#### *Revenues*

## Edgar Filing: OSCIENT PHARMACEUTICALS CORP - Form 10-Q

Total revenues decreased 21% to approximately \$18,366,000 for the three-month period ended March 31, 2008 from approximately \$23,199,000 for the three-month period ended March 31, 2007.

---

**Table of Contents**

Product sales decreased 17% to approximately \$18,269,000 for the three-month period ended March 31, 2008 from approximately \$22,043,000 for the three-month period ended March 31, 2007 due to lower volume of FACTIVE shipments during the quarter of approximately \$3,749,000 along with higher returns of FACTIVE of approximately \$327,000 as a result in the shift of product demand from seven-day course of treatment to five-day course of treatment during the first quarter of 2008 offset by a slight increase in shipments in ANTARA capsules of approximately \$302,000.

Other revenues decreased 92% to approximately \$97,000 for the three-month period ended March 31, 2008 from approximately \$1,156,000 for the three-month period ended March 31, 2007. In the three-month period ended March 31, 2007, other revenue included revenues from the milestone payment from Abbott Canada as a result of obtaining regulatory approval for the fill-finish of FACTIVE drug production for Canada and amortization of upfront license fees received from each of Pfizer Mexico and Menarini, both of which took place in the first quarter of 2007. These revenues did not recur in the three-month period ended March 31, 2008. The Company does not believe that other revenues will be a significant contributor to revenues in the future.

***Costs and Expenses***

Total costs and expenses increased 2% to approximately \$32,001,000 for the three-month period ended March 31, 2008 from approximately \$31,273,000 for the three-month period ended March 31, 2007.

Cost of product sales decreased 20% to approximately \$7,016,000 for the three-month period ended March 31, 2008 from approximately \$8,754,000 for the three-month period ended March 31, 2007 due to decreased shipments of FACTIVE tablets during the first quarter of 2008. Our overall gross product margin at March 31, 2008 and 2007, including amortization of intangible assets was 62% and 60%, respectively. The increase in margin is the result of a slight increase in shipment of ANTARA capsules which have a higher gross margin than FACTIVE. Included in the cost of product sales is approximately \$1,192,000 of amortization of intangibles assets associated with FACTIVE for each of the three-month periods ended March 31, 2008 and 2007, respectively, as well as approximately \$1,085,000 of amortization of intangible assets associated with ANTARA for each of the three-month periods ended March 31, 2008 and 2007, respectively.

Research and development expenses decreased 11% to approximately \$1,343,000 for the three-month period ended March 31, 2008 from approximately \$1,505,000 for the three-month period ended March 31, 2007. Research and development expenses primarily consist of salaries and related expenses for personnel as well as the cost of materials used in research and development. Other research and development expenses include fees paid to consultants and outside service providers. The decrease is due to the completion of enrollment in the FACTIVE post-marketing study in February 2007. As of March 31, 2008, there was no clinical trial accrual balance remaining and we do not believe there will be significant costs associated with clinical trials in the immediate future.

Selling and marketing expenses increased 13% to approximately \$19,752,000 for the three-month period ended March 31, 2008 from approximately \$17,455,000 for the three-month period ended March 31, 2007. This increase was a result of increased costs associated with travel and meeting expenses of approximately \$1,235,000 and higher publication and media related costs of approximately \$429,000 related to the promotion of ANTARA and FACTIVE as well as other selling and marketing expenses of approximately \$167,000. Additionally, the increase was due to higher sample expense of approximately \$288,000 due to the promotion of FACTIVE during the winter season along with costs associated with regional and national sales and training programs of approximately \$988,000. These increases were offset by decreased costs associated with the utilization of a contracted third party sales organization of approximately \$810,000.

General and administrative expenses increased 9% to approximately \$3,890,000 for the three-month period ended March 31, 2008 from approximately \$3,559,000 for the three-month period ended March 31, 2007. The increase is a result of an increase in consulting costs associated with business development activities of approximately \$333,000 and an increase in other general and administrative expenses of approximately \$77,000, offset by a decrease in stock-based compensation expense of approximately \$79,000.

***Other Income and Expense***

Interest income decreased 27% to approximately \$356,000 for the three-month period ended March 31, 2008 from approximately \$491,000 for the three-month period ended March 31, 2007 reflecting lower cash balances and lower interest rate yields from investments during the quarter ended March 31, 2008.



**Table of Contents**

Interest expense significantly increased 86% to approximately \$8,314,000 for the three-month period ended March 31, 2008 from approximately \$4,478,000 for the three-month period ended March 31, 2007. For the three-month period ended March 31, 2008, interest expense primarily consisted of the following:

3.50% Senior convertible promissory notes	\$ 1,940
Accretion of bond discount	3,095
5% Convertible promissory notes	201
Revenue interest assignment	1,908
12% Senior secured note	641
Amortization of deferred financing costs	389
Other	140
	\$ 8,314

Loss on derivatives related to convertible notes was approximately \$44,000 for the three-month period ended March 31, 2008. This loss consists of a non-cash loss resulting from changes in the fair value of the interest make-whole derivative included in our 3.50% convertible senior notes due 2011 which were issued in May 2007 of approximately \$86,000 offset by approximately \$42,000 related to a non-cash gain from changes in the fair value of the derivative related to the financing associated with the acquisition of ANTARA issued in August 2006.

For the three-month period ended March 31, 2008, we recorded a gain on the disposition of investment of approximately \$317,000 related to Agencourt Bioscience Corporation which was acquired by Beckman Coulter.

**Liquidity and Capital Resources**

Our primary sources of cash have been from the sale of debt and equity securities, including royalty-based financing arrangements, product discovery alliances, and the sale of ANTARA capsules and FACTIVE tablets.

As of March 31, 2008, we had total cash, cash equivalents, and restricted cash of approximately \$42,111,000, which includes approximately \$4,198,000 in restricted cash. We believe that based on our available capital, anticipated cash generated from operations and our ability to manage expenses, the cash on hand as of March 31, 2008, is sufficient to fund continuing operations through at least the end of the first quarter of 2009. We most likely will need to raise additional capital within the next 12 months through the issuance of debt or equity securities and/or refinance our existing debt. There is no assurance, however, that changes in our plans or events affecting our operations will not result in accelerated or unexpected expenditures.

In recent years, we have experienced a significant increase in hiring and employment costs in an effort to build an effective sales and marketing organization to commercialize our products, expand the medical/development organization to support additional development and commercialization of our products and to build the infrastructure necessary to support these efforts. We expect expenses in the sales and marketing areas to reflect continued commercialization of ANTARA and FACTIVE as we seek to grow our sales.

**Cash Flows**

Our operating activities used cash of approximately \$11,073,000 and \$6,573,000 for the three-month periods ended March 31, 2008 and 2007, respectively.

Cash used in our operating activities for three-month period ended March 31, 2008 was primarily a result of our net loss of approximately \$21,417,000, decreases in accounts payable of approximately \$773,000 as a result of timing of vendor payments, decreases in accrued expenses and other liabilities of approximately \$617,000 related to timing of vendor invoices, decreases in accrued facilities impairment charges of approximately \$575,000 related to our west coast facility, decreases in deferred revenue of approximately \$91,000 as a result of recognizing Pfizer Mexico revenues upon achievement of milestones in 2007, increases in prepaid expenses and other current assets of approximately \$760,000 resulting from increases in costs associated with the refinancing of the convertible debt transaction, as well as a gain on disposition of investment of approximately \$317,000.

## Edgar Filing: OSCIENT PHARMACEUTICALS CORP - Form 10-Q

These uses of cash were partially offset by decreases in accounts receivable of approximately \$4,407,000 resulting from higher collections on customer balances as of March 31, 2008, decreases in inventory of approximately \$1,478,000 resulting from shipments of ANTARA and FACTIVE as well as tighter inventory management controls, and increases in accrued other long term liabilities of approximately \$730,000 primarily resulting from the accrual of interest on the \$20,000,000 Note Purchase Agreement with Paul Capital. Additional offsets to uses of cash include non-cash depreciation and amortization expenses of approximately \$2,404,000, stock-based compensation of approximately \$578,000, provision for excess and obsolete inventories of approximately \$220,000, loss on derivatives of approximately \$44,000 as well as non-cash interest expenses of approximately \$3,616,000.

**Table of Contents**

Cash used in our operating activities for three-month period ended March 31, 2007 was primarily a result of our net loss of approximately \$11,962,000, decreases in accounts payable of approximately \$1,805,000 as a result of timing of vendor payments, decreases in accrued expenses and other liabilities of approximately \$1,483,000 related to timing of vendor invoices, decreases in accruals established in purchase accounting related to the acquisition of ANTARA and decreases in accrued payroll as a result of the timing of the end of the quarter, decreases in accrued facilities impairment charges of approximately \$644,000 related to our west coast facility, decreases in deferred revenue of approximately \$399,000 as a result of recognizing Pfizer Mexico and Abbott Canada revenues upon achievement of milestones, and increases in prepaid expenses and other current assets of approximately \$43,000 resulting from increases in costs associated with the refinancing of the convertible debt transaction, as well as a gain on disposition of investment of approximately \$158,000.

These uses of cash were partially offset by increases in accrued other long-term liabilities of approximately \$721,000 resulting from the accrual of interest on the \$22,310,000 convertible debt due February 2009, decreases in accounts receivable of approximately \$2,864,000 resulting from higher collections on customer balances including the receipt of \$1.0 million from Menarini related to the FACTIVE European transaction, decreases in inventory of approximately \$2,665,000 resulting from sales of FACTIVE during its peak season of December through March. Additional offsets to uses of cash include non-cash depreciation and amortization expenses of approximately \$2,489,000, stock-based compensation of approximately \$702,000, provision for excess and obsolete inventories of approximately \$130,000, as well as non-cash interest expenses of approximately \$350,000.

Our investing activities provided cash of approximately \$633,000 for the three-month period ended March 31, 2008 and used cash of approximately \$98,000 for the three-month period ended March 31, 2007, respectively. Cash provided by our investing activities for the three-month period ended March 31, 2008 was primarily related to proceeds from repayment of notes receivable of approximately \$421,000 and proceeds from the disposition of investment of approximately \$317,000 offset by purchases of property and equipment of approximately \$70,000 and increases in other assets of approximately \$35,000

Cash used by our investing activities for the three-month period ended March 31, 2007 was primarily related to an increase in other assets of approximately \$240,000 and an increase of approximately \$191,000 in restricted cash offset by proceeds from repayment of notes receivable of approximately \$173,000 and proceeds from the disposition of investment of approximately \$158,000.

Our financing activities provided cash of approximately \$85,000 and \$360,000 for the three-month periods ended March 31, 2008 and 2007, respectively. Cash provided by our financing activities for the three-month period ended March 31, 2008 was primarily due to proceeds from the issuance of 73,533 shares of stock under the employee stock purchase plan of approximately \$94,000 offset by payments on long-term obligation of approximately \$9,000.

Cash provided by our financing activities for the three-month period ended March 31, 2007 was primarily due to proceeds from exercise of 2,769 stock options of approximately \$9,000 and proceeds from the issuance of 83,642 shares of stock under the employee stock purchase plan of approximately \$360,000 offset by payments on long-term obligation of approximately \$9,000.

At December 31, 2007, we had net operating loss carryforwards of approximately \$457,708,000 and \$319,468,000 available to reduce federal and state taxable income, if any, respectively. The net operating loss and tax credit carryforwards expire in 2008 through 2026. In addition, we also had tax research credit carryforwards of approximately \$17,343,000 to reduce federal and state income tax, if any. Net operating loss carryforwards are subject to review and possible adjustment by the Internal Revenue Service and may be limited in the event of certain cumulative changes in ownership interests of significant shareholders over a three-year period in excess of 50%. This potential limitation may result in the expiration of some of our carryforwards prior to utilization. Additionally, certain of our losses have already begun to expire.

*Our Outstanding Debt Obligations and Equity Financings*

On February 6, 2004, in connection with our merger with Genesoft, we issued approximately \$22,310,000 in principal amount of our 5% convertible five year promissory notes due February 2009 (the 2009 Notes ). Following the exchange offer completed in May 2007 described below, there are approximately \$13,300,000 principal amount of the 2009 Notes outstanding at March 31, 2008 which have been classified as short-term obligations on the consolidated balance sheets. The 2009 Notes are convertible into our common stock at the option of the holders, at a conversion price of \$53.13 per share, as adjusted pursuant to the reverse stock split which we effectuated in November 2006.

On June 26, 2004, we issued \$152,750,000 in principal amount of our 3 1/2% senior convertible promissory notes due in April 2011 (the Original 2011 Notes ). Following the exchange offer completed in May 2007 described below, there are approximately \$829,000 principal amount of the Original 2011 Notes outstanding at March 31, 2008. These notes are convertible into our common stock at the option of the holders at a conversion price of \$53.14 per share, as adjusted pursuant



**Table of Contents**

to the reverse stock split which we effectuated in November 2006. We may not redeem the outstanding Original 2011 Notes at our election before May 10, 2010. After this date, we can redeem all or a part of the Original 2011 Notes for cash at a price equal to 100% of the principal amount of the notes to be redeemed plus accrued and unpaid interest. The holders' right of repurchase under the Original 2011 Notes is identical to the right of repurchase under the New Notes (defined below) and is described below.

In May 2007, we completed (i) an exchange offer with certain holders of the Original 2011 Notes in which we exchanged \$151,921,000 aggregate principal amount of our new 3.50% Convertible Senior Notes due 2011 (the New Notes) for \$151,921,000 aggregate principal amount of our then outstanding Original 2011 Notes; and (ii) an exchange offer with holders of the 2009 Notes in which we exchanged approximately \$10,574,000 aggregate principal and accrued interest amount of our then outstanding 2009 Notes for approximately \$13,746,000 aggregate principal amounts of the New Notes. We also issued an additional \$60,000,000 of New Notes to the public for cash at a public offering price of 77.5% of principal resulting in \$46,500,000 in gross proceeds to us.

The New Notes are initially convertible into approximately 16,718,000 common shares at a conversion rate of 74.074 of our common shares per \$1,000 principal amount of New Notes, which is equivalent to a conversion price of approximately \$13.50 per common share. The New Notes are convertible at any time by the holder. In the event of a fundamental change, holders of the Original 2011 Notes and the New Notes have the right to require us to repurchase all or any portion of their notes at a price equal to 100% of the principal amount plus accrued and unpaid interest. Under the indenture for the Original 2011 Notes and the New Notes, a fundamental change will be deemed to occur if (i) a change of control transaction occurs in which substantially all of our common stock is exchanged either for consideration other than common stock that is listed on a U.S. national securities exchange or is exchanged for consideration other than common stock that is approved for quotation on a U.S. system of automated dissemination of quotations of securities or (ii) our common stock is neither listed for trading on a U.S. national securities exchange nor approved for listing on any U.S. system of automated dissemination of quotations of securities prices.

Before May 10, 2010, we may not redeem the New Notes. On or after May 10, 2010, we may redeem any or all of the New Notes at 100% of the principal amount, plus accrued and unpaid interest. In addition, we may automatically convert some or all of the New Notes on or prior to the maturity date if the closing price of its common shares has exceeded 130% of the conversion price then in effect for at least 20 trading days during any consecutive 30 trading day period ending within five trading days prior to the notice of auto-conversion (the auto-conversion feature). If a holder elects to voluntarily convert their New Notes or we elect to automatically convert some or all of the New Notes on or prior to May 10, 2010, we will pay additional interest to holders of New Notes being converted. This additional interest will be equal to the amount of interest that would have been payable on the New Notes from the last day interest was paid on the New Notes, through and including May 10, 2010. Additional interest, if any, will be paid in cash or in our common shares, at our option. If we pay additional interest upon a voluntary conversion with our common shares, such shares will be valued at the conversion price that is in effect at that time. If we pay additional interest upon an automatic conversion with our common shares, such shares will be valued at 90% of the automatic conversion price that is in effect at that time.

The additional New Notes generated gross proceeds of \$46,500,000. Debt issuance costs, related to the New Notes, of approximately \$6,057,000 are being amortized to interest expense, on a straight-line basis over the 48 month period to maturity of the notes. As of March 31, 2008, the fair value of the derivative is approximately \$153,000 which reflects a change in the fair value of approximately \$130,000 which is included as a loss on derivative in the consolidated statements of operations.

For the three-month period ended March 31, 2008, we incurred approximately \$2,149,000 in interest expense on our convertible debt, which is payable on a semi-annual basis. Additionally, we amortized approximately \$3,095,000 as non-cash interest expense related to the accretion of the bond discount and approximately \$389,000 in new debt issuance costs.

*Other Financial Arrangements*

To finance the acquisition of ANTARA in August 2006, we, together with our wholly-owned subsidiary Guardian II Acquisition Corporation, or Guardian II (the entity which holds all of the ANTARA assets), entered into several financing agreements with Paul Royalty Fund Holdings II, LP, an affiliate of Paul Capital Partners, or Paul Capital, including the Revenue Interests Assignment Agreement, the Note Purchase Agreement and the Common Stock and Warrant Purchase Agreement, in consideration for an aggregate amount of \$70 million.

Under the Revenue Interests Assignment Agreement (the Revenue Agreement), we sold to Paul Capital the right to receive specified royalties on our net sales in the United States (and the net sales of our affiliates and licensees) of FACTIVE tablets and Guardian II sold to Paul Capital the right to receive specified royalties on Guardian II's net sales in the United States (and the net sales of its respective affiliates and licensees) of the ANTARA capsules, in each case until December 31,



**Table of Contents**

2016. The royalty payable to Paul Capital on net sales of ANTARA capsules and FACTIVE tablets starts each fiscal year as a high single-digit royalty rate and could decline to a low single-digit royalty rate based on achievement of annual specified sales thresholds in each fiscal year. Once the cumulative royalty payments to Paul Capital exceed \$100 million, the royalties become nominal.

In connection with the Revenue Agreement, we recorded a liability, referred to as the revenue interest liability, of approximately \$40,000,000 in accordance with EITF No. 88-18, *Sales of Future Revenues* (EITF No. 88-18). We impute interest expense associated with this liability using the effective interest rate method and have recorded a corresponding accrued interest liability. The effective interest rate is calculated based on the rate that would enable the debt to be repaid in full over the life of the arrangement. The interest rate on this liability may vary during the term of the agreement depending on a number of factors, including the level of ANTARA and FACTIVE sales. Payments made to Paul Capital as a result of ANTARA and FACTIVE sales levels will reduce the accrued interest liability and the principal amount of the revenue interest liability. We currently estimate that the imputed interest rate associated with this liability will be approximately 19.97%. We recorded approximately \$1,908,000 in interest expense related to this agreement in the three-month period ended March 31, 2008. Through March 31, 2008, there have been no principal payments made to Paul Capital as a result of ANTARA or FACTIVE sales.

In the event of (i) a change of control of Oscient or Guardian II, (ii) a bankruptcy of Oscient or Guardian II, (iii) a transfer by Oscient or any of its subsidiaries of substantially all of either ANTARA or FACTIVE, (iv) subject to a cure period, breach of certain material covenants and representations in the Revenue Agreement and (v) in the event the sale of ANTARA is suspended due to a court issued injunction or we elect to suspend sales of ANTARA, in each case as a result of a lawsuit by certain third parties (each a Put Event), Paul Capital has the right to require Oscient and Guardian II to repurchase from Paul Capital its royalty interest at a price in cash which equals the greater of (a) a specified multiple of cumulative payments made by Paul Capital under the Revenue Agreement less the cumulative royalties previously paid to Paul Capital; or (b) the amount which will provide Paul Capital, when taken together with the royalties previously paid, a specified rate of return (the Put/Call Price). Upon a bankruptcy event, Oscient and Guardian II are automatically required to repurchase the Paul Capital royalty interest at the Put/Call Price. In the event of a change of control of Oscient, we have the right to repurchase the Paul Capital royalty interest for an amount equal to the Put/Call Price. We have determined that Paul Capital's put option and our call option meet the criteria to be considered an embedded derivative and should be accounted for as such. We recorded a net liability of \$1,005,000 related to the put/call option to reflect its estimated fair value as of the date of the agreement, in accordance with SFAS No. 133. This liability is revalued on a quarterly basis to reflect any changes in the fair value and any gain or loss resulting from the revaluation will be recorded in earnings. As of March 31, 2008, the fair value of the derivative is approximately \$944,000 which reflects a change in the fair value of approximately \$42,000 which has been recorded as a gain on derivative in the consolidated statements of operations.

During the first two fiscal years immediately following the fiscal year in which combined annual net sales of ANTARA and FACTIVE are equal to or greater than \$125 million, Oscient and Guardian II have the right, but not the obligation, to reduce the royalty percentages due under the Revenue Agreement to Paul Capital by 50% by paying Paul Capital a price in cash which will provide Paul Capital, when taken together with the royalties previously paid, a specified rate of return. During the first two fiscal years immediately following the fiscal year in which combined annual net sales of ANTARA and FACTIVE are equal to or greater than \$250 million, Oscient and Guardian II have the right, but not the obligation, to repurchase the Paul Capital royalty interest at a price in cash which will provide Paul Capital, when taken together with the royalties previously paid, a specified rate of return.

Guardian II entered into a Note Purchase Agreement, or the Note Purchase Agreement, with Paul Capital pursuant to which Guardian II issued and sold a \$20,000,000 aggregate principal amount of 12% senior secured note, or the Note, due on the fourth anniversary of the closing date, subject to Guardian II's option to extend the maturity to the sixth anniversary of the closing date, provided (i) there are no defaults under the Note at the time, and (ii) we issue to Paul Capital, at the time of the exercise of such option, a warrant for a number of shares of common stock equal to 10% of the principal balance plus accrued interest divided by \$6.94, with an exercise price of \$6.94 per share. If we exercise such option, the number of shares subject to the warrant issuable to Paul Capital would be between 288,018 shares and 367,529 shares, depending upon the amount, if any, of the interest payable on the Note we elect to have added to the principal of the Note rather than paid in cash as described below.

Interest is payable semi-annually in arrears on the last day of each of March and September. Guardian II has the option to pay interest in cash or to have 50% of the interest paid in cash and 50% of the interest added to principal. In the event of a change of control of Oscient or on or after the second anniversary of the closing, Oscient and Guardian II may at our option prepay all or any part of the Note at a premium which declines over time. In the event of an event of default, with event of default defined as a continuing Put Event under the Revenue Agreement as described in more detail above, the outstanding principal and interest in the Note will become immediately due and payable. From inception of the Note Purchase

---

## **Table of Contents**

Agreement, we exercised our option to add interest expense payable to the principal of the Note. As of March 31, 2008, the amount added to the principal was approximately \$2,015,000. This amount is recorded as other long-term liabilities on the consolidated balance sheets.

Subject to the Revenue Agreement and the Note Purchase Agreement, without the prior written consent of Paul Capital, Oscient and Guardian II have agreed not to (i) amend, waive any rights under, or terminate any material license agreements, including the agreements relating to the ANTARA and FACTIVE products, (ii) enter into any new agreement or amend or fail to exercise any of its material rights under existing agreements that would adversely affect Paul Capital's royalty interest, and (iii) sell any material assets related to ANTARA or FACTIVE.

Pursuant to the terms of the Revenue Agreement and the Note Purchase Agreement, Guardian II and Paul Capital entered into a Security Agreement, or the Security Agreement, under which Guardian II granted to Paul Capital a security interest in and to substantially all assets owned by Guardian II (including rights to the ANTARA products) in order to secure its performance under each of the Revenue Agreement, the Note Purchase Agreement and the Note. To the extent the indebtedness under certain of our pre-existing debt obligations is refinanced or replaced and such replacement or refinancing indebtedness is secured, we have agreed to equally and ratably secure its obligations under the Revenue Agreement.

As part of the financing, we and Paul Capital also entered into a Common Stock and Warrant Purchase Agreement, or the Stock and Warrant Purchase Agreement, pursuant to which, in exchange for \$10 million, Oscient sold to Paul Capital 1,388,889 shares (the Shares) of the Common Stock, at a price of \$7.20 per share (the Private Placement) and issued Paul Capital a warrant (the Warrant) to purchase 288,018 shares of Common Stock (the Warrant Shares) at an exercise price of \$6.94 per share. The Warrant is exercisable for seven years from the date of closing. The Warrant contains a net share settlement feature and penalties if Oscient does not deliver the applicable amount of Warrant Shares within three trading days of exercise of a Warrant by Paul Capital. The Warrant also contains provisions providing that, at Paul Capital's election, Oscient must re-purchase the Warrant from Paul Capital upon a sale of the Company in which the consideration for such sale is solely cash. The warrant has not been exercised as of March 31, 2008. We agreed, pursuant to the Stock and Warrant Purchase Agreement, to elect one person designated by Paul Capital to our Board of Directors following the closing and to continue to nominate one person designated by Paul Capital for election to our Board of Directors by our shareholders. The director designated by Paul Capital shall resign and we shall no longer be required to nominate a director designated by Paul Capital upon the later of the following events: (1) if Paul Capital ceases to own at least five percent of our Common Stock or securities convertible into our Common Stock; (2) if we owe Paul Capital less than \$5,000,000 under the Note pursuant to the Note Purchase Agreement; (3) the cumulative payments to Paul Capital made by us under the terms of the Revenue Agreement first exceed 250% of the consideration paid to us by Paul Capital; or (4) if the amounts due by us pursuant to the Revenue Agreement cease to be due. If at any time Paul Capital's designee is not elected to our Board of Directors, Paul Capital's designee will have a right to participate in all meetings of our Board of Directors in a nonvoting observer capacity.

## **Contractual Obligations**

For the three-month period ended March 31, 2008, there were no material changes to our contractual obligations outside the ordinary course of business.

## **ITEM 3: QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Our market risks, and the ways we manage them, are summarized under the captions Management's Discussion and Analysis of Financial Condition and Results of Operations and Quantitative and Qualitative Disclosures About Market Risk, each included in our Form 10-K for the year ended December 31, 2007. There have been no material changes in information affecting our market risk since the end of the fiscal year ended December 31, 2007. Our Annual Report on Form 10-K was filed with the Securities and Exchange Commission on February 6, 2008.

## **ITEM 4: CONTROLS AND PROCEDURES**

Our management, under the supervision and with the participation of our Chief Executive Officer (CEO) and Chief Financial Officer (CFO), has evaluated the effectiveness of our disclosure controls and procedures as defined in Securities and Exchange Commission (SEC) Rule 13a-15(e) as of the end of the period covered by this report. Based upon that evaluation, management has concluded that our disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Securities Exchange Act of 1934 is communicated to management, including the CEO and CFO, as appropriate to allow timely decisions regarding required disclosure and is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.





## **Table of Contents**

During the period covered by this report, there have been no significant changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II OTHER INFORMATION**

### **ITEM 1: LEGAL PROCEEDINGS**

From time to time we are involved in legal actions in the normal course of business, some of which seek monetary damages, including claims for punitive damages. These actions, when finally concluded and determined, will not, in our opinion, have a material adverse effect on our financial position, results of operations or cash flows.

We believe that we have obtained adequate insurance or, where appropriate, have established adequate reserves in connection with these legal proceedings.

### **ITEM 1A: RISK FACTORS**

Some of the important risk factors that could cause our actual results to differ materially from those expressed in our forward-looking statements include, but are not limited to, the following:

#### **RISKS RELATED TO OUR BUSINESS**

The following are significant factors known to us that could materially adversely affect our business, financial condition, or operating results. The risks described below are not the only risks facing us. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

#### **We have a history of significant operating losses and expect losses to continue for some time.**

We have a history of significant operating losses and expect losses to continue for some time. We expect to continue to have net losses in the near future and we had an accumulated deficit of approximately \$467,174,000 as of March 31, 2008. These losses are primarily a result of costs incurred in research and development, including our clinical trials and product acquisitions, from sales and marketing, and from general and administrative costs associated with our operations and product sales. These costs have exceeded our revenues which to date have been generated principally from sales of ANTARA and FACTIVE, sublicensing agreements, and our legacy collaborations, government grants and sequencing services.

We anticipate that we will incur additional losses in the current year and in future years. These losses are expected to continue, principally due to the expenses in the sales and marketing area, as we seek to grow sales of ANTARA capsules and FACTIVE tablets and as we seek to acquire additional approved products or product candidates. Additionally, our partners' product development efforts that utilize our genomic discoveries are at an early stage and, accordingly, we do not expect our losses to be substantially mitigated by revenues from milestone payments or royalties under those agreements for a number of years, if ever.

#### **Our business is very dependent on the commercial success of ANTARA and FACTIVE.**

ANTARA capsules and FACTIVE tablets are currently our only commercial products and we expect that they will likely account for substantially all of our product revenues for at least the next several years or until we successfully acquire, in-license or enter into co-promotion agreements for additional products.

ANTARA is approved by the FDA to treat hypercholesterolemia (high blood cholesterol) and hypertriglyceridemia (high triglycerides) in combination with a healthy diet. FACTIVE tablets have FDA marketing approval for the treatment of community-acquired pneumonia of mild to moderate severity, or CAP, and acute bacterial exacerbations of chronic bronchitis, or AECB. The commercial success of ANTARA and FACTIVE will depend upon their continued acceptance by regulators, physicians, patients and other key decision-makers as a safe, therapeutic and cost-effective alternative to other products used, or currently being developed, to treat CAP and AECB, in the case of FACTIVE tablets, or hypercholesterolemia and hypertriglyceridemia, in the case of ANTARA capsules. In addition, if concerns should arise about the safety or efficacy of our products, regardless of whether or not such concerns have a basis in generally accepted science or peer-reviewed scientific

## Edgar Filing: OSCIENT PHARMACEUTICALS CORP - Form 10-Q

research, such concerns could adversely affect the market for these products. Furthermore, regulatory authorities may withdraw the approval of our products, or require the addition of restrictive safety labeling statements, to our products. Any of these events could prevent us from achieving or maintaining market acceptance of the product or could substantially increase the costs and expenses of commercializing the product, which in turn could delay or prevent us from generating significant revenues from its sale. If ANTARA and FACTIVE are not commercially successful, we will have to find additional sources of funding or curtail or cease operations.

---

## **Table of Contents**

**If third parties challenge the validity of the patents or proprietary rights of our marketed products or assert that we have infringed their patents or proprietary rights, we may become involved in intellectual property disputes and litigation that would be costly, time consuming, and prevent the commercialization of ANTARA, FACTIVE and/or any other products that we acquire.**

The intellectual property rights of pharmaceutical companies, including us, are generally uncertain and involve complex legal, scientific and factual questions. Our success in developing and commercializing pharmaceutical products may depend, in part, on our ability to operate without infringing on the intellectual property rights of others and to prevent others from infringing on our intellectual property rights. There has been substantial litigation regarding patents and other intellectual property rights in the pharmaceutical industry. For example, third parties seeking to market generic versions of branded pharmaceutical products often file an Abbreviated New Drug Application ( ANDA ) with the FDA, wherein such ANDA contains a certification by the applicant that the patents protecting the branded pharmaceutical product are invalid, unenforceable and/or not infringed, a so-called Paragraph IV certification. As described under, Our products and product candidates face significant competition in the marketplace. Teva recently filed such an ANDA containing a Paragraph IV certification with the FDA seeking the approval of a generic version of Tricor® 145 mg. If such a filing is made referencing either ANTARA or FACTIVE, we may need to defend and/or assert our patents, including filing lawsuits alleging patent infringement, which would be extremely costly to us. If we were unsuccessful in such a proceeding and the FDA approved a generic version of any one or both of our products, such an outcome would have a material adverse effect on our business.

We may also become party to patent litigation or proceedings at the U.S. Patent and Trademark Office or a foreign patent office to determine our patent rights with respect to third parties which may include competitors in the pharmaceutical industry. Interference proceedings in the U.S. Patent and Trademark Office or opposition proceedings in a foreign patent office may be necessary to establish which party was the first to discover such intellectual property. The cost to us of any patent litigation or similar proceeding could be substantial, and it may absorb significant management time.

We do not expect to maintain separate insurance to cover intellectual property infringement. Our general liability insurance policy does not cover our infringement of the intellectual property rights of others. If infringement litigation against us is resolved unfavorably, we may be enjoined from manufacturing or selling certain of our products or services and be liable for damages. In certain cases, a license may be available, although we may not be able to obtain such a license on commercially acceptable terms, or at all.

We are aware of United States patents that are controlled by third parties that may be construed to encompass ANTARA. However, we believe that, if these patents were asserted against us, we would have valid defenses that ANTARA does not infringe any valid claims of these patents or that the patents would be found to be unenforceable. Nonetheless, in order to successfully challenge the validity of any United States patent, we would need to overcome the presumption of validity which is accorded to issued patents in the United States. If any of these patents were found to be valid and enforceable and we were found to infringe any of them, or any other patent rights of third parties, we would be required to pay damages, cease the sale of ANTARA or pay additional royalties on manufacture and sales of ANTARA. If we are unable to market or sell ANTARA, or if we are obligated to pay significant damages or additional royalties, our earnings attributable to ANTARA would be reduced and our business would be materially adversely affected. Even if we prevail, the cost to us of any patent litigation would likely be substantial, and it may absorb significant management time. If the other party in any such litigation has substantially greater resources than us, we may be forced, due to cost constraints, to seek to settle any such litigation on terms less favorable to us than we might be able to obtain if we had greater resources.

### **Our debt obligations expose us to risks that could adversely affect our business, operating results and financial condition.**

We have a substantial level of debt. As of March 31, 2008, we had approximately \$310.1 million of indebtedness outstanding (including accrued interest and excluding a bond discount of approximately \$43.1 million), which includes approximately \$41.6 million in revenue interest that entitles Paul Capital to receive a royalty on the sales of both ANTARA and FACTIVE. Approximately \$16.3 million of outstanding indebtedness will mature in 2009, approximately \$22.0 million of outstanding indebtedness will mature in 2010 or it may be extended at our option to 2012 through issuance of warrants and approximately \$230.2 million of indebtedness will mature in 2011. Included in the above is the exchange offer completed on May 1, 2007 relating to the existing convertible debt and a new debt offering of \$60 million which generated net proceeds to the Company of approximately \$40.4 million. The level and nature of our indebtedness, among other things, could:

make it difficult for us to make payments on our debt outstanding from time to time or to refinance it;

## Edgar Filing: OSCIENT PHARMACEUTICALS CORP - Form 10-Q

make it difficult for us to obtain any necessary financing in the future for working capital, capital expenditures, debt service, acquisitions or general corporate purposes;

limit our flexibility in planning for or reacting to changes in our business;

---

**Table of Contents**

reduce funds available for use in our operations;

impair our ability to incur additional debt because of financial and other restrictive covenants;

make us more vulnerable in the event of a downturn in our business;

place us at a possible competitive disadvantage relative to less leveraged competitors and competitors that have better access to capital resources;

restrict the operations of our business as a result of provisions in the Revenue Interests Agreement with Paul Capital that restrict our ability to (i) amend, waive any rights under, or terminate any material license agreements, including the agreements relating to the ANTARA products and FACTIVE, (ii) enter into any new agreement or amend or fail to exercise any of our material rights under existing agreements that would materially adversely affect Paul Capital's royalty interest, and (iii) sell any material assets related to ANTARA or FACTIVE; or

impair our ability to merge or otherwise effect the sale of the Company due to the right of the holders of certain of our indebtedness to accelerate the maturity date of the indebtedness in the event of a change of control of the company.

If we do not grow our revenues as we expect, we could have difficulty making required payments on our indebtedness. If we are unable to generate sufficient cash flow or otherwise obtain funds necessary to make required payments, or if we fail to comply with the various requirements of our indebtedness, we would be in default, which would permit the holders of our indebtedness to accelerate the maturity of the indebtedness and could cause defaults under any indebtedness we may incur in the future. Any default under our indebtedness would have a material adverse effect on our business, operating results and financial condition.

**We most likely will need to raise additional funds in the future.**

We believe our existing funds, anticipated cash generated from operations and our ability to manage expenses should be sufficient to support our current plans through at least the end of the first quarter of 2009. We most likely will need to raise additional capital and/or refinance our existing debt within the next 12 months to fund our operations and/or other potential commercial or development opportunities, to support our sales and marketing activities, and to fund clinical trials and other research and development activities. We may seek funding through additional public or private equity offerings, debt or other strategic financings or agreements with customers or vendors. Our ability to raise additional capital, however, will be impacted by, among other factors, the investment market for pharmaceutical companies and the progress of the ANTARA and FACTIVE commercial programs, our ability to acquire, in-license or enter into co-promotion agreements for additional products, our progress in finding a development and commercialization partner for Ramoplanin and our progress with other business development transactions. Additional financing may not be available to us when needed, or, if available, may not be available on favorable terms. If we cannot obtain adequate financing on acceptable terms when such financing is required, our business will be adversely affected.

**Future fundraising could dilute the ownership interests of our shareholders.**

In order to raise additional funds, we may issue equity or convertible debt securities in the future. Depending upon the market price of our shares at the time of any transaction, we may be required to sell a significant percentage of the authorized and unissued shares of our common stock in order to fund our operating plans, potentially requiring a shareholder vote. In addition, we may have to sell securities at a discount to the prevailing market price, resulting in further dilution to our shareholders.

**We need to continue to develop marketing and sales capabilities to successfully commercialize ANTARA capsules, FACTIVE tablets and our other product candidates.**

ANTARA capsules and FACTIVE tablets are the first two FDA-approved products which we license and promote. To date, we still have limited marketing and sales experience. The continued development of these marketing and sales capabilities, including any expansion of our sales force, will require significant expenditures, management resources and time. Failure to establish sufficient sales and marketing capabilities in a timely and regulatory compliant manner may adversely affect our ability to continue to grow the ANTARA and FACTIVE brands and related

product sales.

**Our products and product candidates face significant competition in the marketplace.**

*ANTARA*

ANTARA is a fenofibrate product approved by the FDA to treat hypercholesterolemia and hypertriglyceridemia in combination with a healthy diet. The marketing of current and additional branded versions of fenofibrate could reduce our net sales of ANTARA and adversely impact our revenues. The primary competition for ANTARA in the fenofibrate market is

---

## Table of Contents

Tricor® 145 mg, a product manufactured by Abbott Laboratories, which accounted for approximately 91% of U.S. fenofibrate sales for the three-month period ended March 31, 2008. Abbott has announced its development and evaluation of another branded fenofibrate-type product, both as mono and combination therapy.

In addition to Tricor, there are several other branded fenofibrate products which compete with ANTARA. ANTARA also competes with Triglide®, a 160 mg fenofibrate product marketed by Sciele Pharma, Inc., which accounted for approximately 2% of U.S. fenofibrate sales for the three-month period ended March 31, 2008. Additionally, ANTARA competes with Lipofen®, a 150 mg fenofibrate product, which was recently launched and is currently being marketed by ProEthic Pharmaceuticals, Inc. ANTARA also competes with Fenoglide, a 120 mg branded fenofibrate product, which had been filed with the FDA in late 2006 by LifeCycle Pharma referencing ANTARA in accordance with the provisions of section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act. LifeCycle Pharma subsequently granted Sciele Pharmaceuticals, which recently launched the product, the rights to market Fenoglide in North America.

Additionally, several generic versions of fenofibrate in varying doses are also available for the treatment of dyslipidemias. Revenues from these products accounted for approximately 3% of total U.S. sales of fenofibrate sales in the first quarter of 2008. In May 2005, Teva Pharmaceutical Industries, Ltd. (Teva) obtained FDA approval to market a generic version of Abbott Laboratories' 160 mg Tricor tablet (which is no longer marketed or sold). In addition, Solvay S.A., Abbott Laboratories' partner announced on January 23, 2008, that Teva had filed an Abbreviated New Drug Application (ANDA) with a Paragraph IV certification seeking the approval of a generic version of Tricor 145 mg. If a generic version of Abbott Laboratories' Tricor 145 mg product is approved by the FDA, the percentage of total revenues attributable to generic fenofibrate products would likely increase. There are also several other FDA-approved products and products in development for similar indications as ANTARA which could compete with ANTARA, including statins, omega-3 fatty acids, niacin, ezetimibe and fixed-dose combination products.

The growth of any of these competitive branded products, the marketing of generic fenofibrate products or the FDA approval and subsequent marketing of products with similar indications including combination therapy products currently in development, could result in a decrease in ANTARA sales, pressure on the price at which we are able to sell ANTARA, reduce our profit margins, reduce our net sales of ANTARA and adversely impact our revenues.

### *FACTIVE*

FACTIVE tablets are approved for the treatment of community-acquired pneumonia of mild to moderate severity and acute bacterial exacerbations of chronic bronchitis. There are several classes of antibiotics that are primary competitors for the treatment of these indications, including other fluoroquinolones (levofloxacin, ciprofloxacin and moxifloxacin), macrolides (clarithromycin and azithromycin), cephalosporins (cefdinir) and penicillins (amoxicillin/clavulanate potassium).

Many generic antibiotics are also currently prescribed to treat these infections. Moreover, a number of the antibiotic products that are competitors of FACTIVE tablets have composition of matter patents which have expired or will expire at dates ranging from 2003 to 2016. As these competitors lose patent protection, their manufacturers will likely decrease their promotional efforts. However, manufacturers of generic drugs will likely begin to produce some of these competing products and this could result in pressure on the price at which we are able to sell FACTIVE tablets and reduce our profit margins.

### *Ramoplanin*

Ramoplanin is in clinical development for the treatment of *Clostridium difficile*-associated disease (CDAD). We are aware of two products currently utilized in the marketplace for the treatment of this indication: Vancocin® pulvules (vancomycin), a product marketed by ViroPharma Inc., and metronidazole, a generic product. We are also aware of several companies with products in development for the treatment of CDAD, as well as the potential approval of generic vancomycin.

Many of our competitors have substantially greater capital resources and human resources than us. Furthermore, many of those competitors are more experienced than us in drug discovery, clinical development and commercialization, and in obtaining regulatory approvals. As a result, those competitors may discover, develop and commercialize pharmaceutical products or services before us. In addition, our competitors may discover, develop and commercialize products or services that are more effective than, or otherwise render non-competitive or obsolete, the products or services that we or our collaborators are seeking to develop and commercialize. Moreover, these competitors may obtain patent protection or other intellectual property rights that would limit our rights or the ability of our collaborators to develop or commercialize pharmaceutical products or services.





---

**Table of Contents**

**Our failure to in-license, co-promote or acquire and develop additional product candidates or approved products will impair our ability to grow.**

As part of our growth strategy, we intend to acquire, develop and commercialize additional product candidates or approved products. The success of this strategy depends upon our ability to identify, select and acquire products that meet our criteria. We may not be able to acquire the rights to additional product candidates and approved products on terms that we find acceptable, or at all. The acquisition of rights to additional products would likely require us to make significant up-front cash payments, which could adversely affect our liquidity and/or may require us to raise additional capital and/or secure external sources of financing. We may seek funding for product acquisitions through equity or debt offerings, through royalty-based financings or by a combination of these methods, such as the financing we completed with Paul Capital to fund the ANTARA acquisition. There is no assurance that we will be able to raise the funds necessary to complete any product acquisitions on acceptable terms or at all. If we raise funds it could dilute shareholders, or if we use existing resources it could adversely affect our liquidity and accelerate our need to raise additional capital.

New product candidates acquired or in-licensed by us may require additional research and development efforts prior to commercial sale, including extensive preclinical and/or clinical testing and approval by the FDA and corresponding foreign regulatory authorities. All product candidates are prone to the risks of failure inherent in pharmaceutical product development, including the possibility that the product candidate will not be safe, effective or approved by regulatory authorities. In addition, it is uncertain whether any approved products that we develop or acquire will be:

manufactured or produced economically;

successfully commercialized; or

widely accepted in the marketplace.

**We, as well as our partners, are subject to numerous complex regulatory requirements and failure to comply with these regulations, or the cost of compliance with these regulations, may harm our business.**

Virtually all aspects of our and our partners' activities are subject to regulation by numerous governmental authorities in the U.S., Europe, Canada, Mexico and elsewhere. These regulations govern or affect the testing, manufacture, safety, effectiveness, labeling, storage, record-keeping, approval, distribution, advertising and promotion of ANTARA, FACTIVE, Ramoplanin and our other product candidates, as well as safe working conditions and the experimental use of animals. We are required to report any serious and unexpected adverse experiences with our products to the FDA and other similar regulatory authorities in other jurisdictions. Noncompliance with any applicable regulatory requirements or failure to obtain adequate documentation from any governmental agency can result in refusal of the government to approve products for marketing, criminal prosecution and fines, recall or seizure of products, injunctions, total or partial suspension of production, whistleblower lawsuits, prohibitions or limitations on the commercial sale of products or refusal to allow the entering into of federal and state supply contracts. These enforcement actions would detract from management's ability to focus on our daily business and would have an adverse effect on the way we conduct our daily business, which could severely impact future profitability. Our corporate compliance program cannot fully ensure that we are in compliance with all applicable laws and regulations, and a failure to comply with such regulations or a failure to prevail in litigation related to noncompliance could harm our business.

For instance, we, along with many other pharmaceutical companies, received correspondence in 2007 from the FDA stating that it had some concerns over the reliability of studies conducted by MDS Pharma Services between 2000 and 2004. The predecessor owner of the rights to ANTARA, Reliant Pharmaceuticals, had engaged MDS Pharma to perform certain bioequivalence studies for ANTARA, including some studies that were submitted in support of the original approval of ANTARA. The FDA suggested that we take one of the following steps to assess the accuracy of such data: conduct an independent audit of the trials to verify the data, re-assay samples or repeat the studies. The FDA also stated that it has not detected any signals or any evidence that the products mentioned in its correspondence pose a safety risk or that there has been any impact on efficacy. We have responded to the FDA informing the FDA that we do not believe that these steps are necessary because the FDA audited the pivotal MDS Pharma study at issue prior to its approval of ANTARA, and further because there are other non-MDS Pharma data that support the safety and effectiveness of ANTARA. Because the outcome of this issue is uncertain, we cannot predict whether this issue will have a material impact on our results of operations.

**New legal and regulatory requirements could make it more difficult for us to obtain expanded or new product approvals, and could limit or make more burdensome our ability to commercialize our approved products.**

Numerous proposals have been made in recent years to impose new requirements on drug approvals, expand post-approval requirements, and restrict sales and promotional activities. Without limiting the generality of the foregoing, Congress has recently enacted, and the President has signed into law, the Food and Drug Administration Amendments Act of 2007 (FDAAA). The recently enacted amendments would among other things, require all new drug applicants to submit risk

**Table of Contents**

evaluation and minimization plans to monitor and address potential safety issues for products upon approval, grant the FDA the authority to impose risk management measures for marketed products and to mandate labeling changes in certain circumstances, and establish new requirements for disclosing the results of clinical trials. Additional measures have also been enacted to address the perceived shortcomings in the FDA's handling of drug safety issues, and to limit pharmaceutical company sales and promotional practices. The implementation of the recently enacted amendments or other proposed legal or regulatory changes may make it more difficult or burdensome for us to obtain extended or new product approvals, and our current approvals may be restricted or subject to onerous post-approval requirements. Such changes may increase our costs and adversely affect our operations. The ability of us or our partners to commercialize approved products successfully may be hindered, and our business may be harmed as a result.

Failure to comply with or changes to the regulatory requirements that are applicable to ANTARA, FACTIVE or our other product candidates may result in a variety of consequences, including the following:

restrictions on our products or manufacturing processes;

notice of violation letters regarding promotional and marketing materials and activities;

withdrawal of the product from the market;

voluntary or mandatory recall of the product;

fines against us or our partners;

suspension or withdrawal of regulatory approvals for ANTARA, FACTIVE or a product candidate which subsequently receives regulatory approval;

suspension or termination of any clinical trials of a product candidate;

refusal to permit import or export of our products;

refusal to approve pending applications or supplements to approved applications that we or our partners submit;

denial of permission to file an application or supplement in a jurisdiction;

product seizure; and

injunctions or the imposition of civil or criminal penalties against us or our partners.

**If we market or distribute products in a manner that violates federal or state healthcare fraud and abuse, marketing disclosure or drug pedigree laws, we may be subject to civil or criminal penalties.**

## Edgar Filing: OSCIENT PHARMACEUTICALS CORP - Form 10-Q

In addition to FDA and related regulatory requirements, we are subject to health care fraud and abuse laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally or state financed health care programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, patients, purchasers and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing, or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, or off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses; and submitting inflated best price information to the Medicaid Rebate Program.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would also harm our financial condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

## **Table of Contents**

In recent years, several states and localities, including California, the District of Columbia, Maine, Minnesota, Nevada, New Mexico, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, and file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar legislation is being considered by Congress and other states. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. We are not aware of any companies against which fines or penalties have been assessed under these special state reporting and disclosure laws to date. Nonetheless, while we have established a compliance program, we may face enforcement, fines and other penalties, and could receive adverse publicity if this program is found not to be in full compliance with these laws.

In recent years, some states have passed or have proposed laws and regulations obligating pharmaceutical manufacturers and distributors to provide prescription drug pedigrees that are intended to protect the safety of the drug supply channel. For example, the Florida Prescription Drug Pedigree laws and regulations that became effective in July 2006 imposed obligations upon us to deliver prescription drug pedigrees to various categories of customers. At the federal level, the FDA issued final regulations pursuant to the Pharmaceutical Drug Marketing Act that became effective in December 2006. Also, effective January 1, 2011, California will require the implementation of costly track and trace chain of custody technologies. Compliance with these pedigree laws requires implementation of extensive tracking systems as well as heightened documentation and coordination with distributors and customers. While we fully intend to comply with these laws, there is uncertainty around the interpretation of the recently passed laws, future changes in legislation and government enforcement of these laws. Failure to comply could result in fines or penalties, as well as loss of business that could have a material adverse effect on our business.

### **We depend on third parties to manufacture and distribute our products and product candidates.**

We do not have the internal capability to manufacture pharmaceutical products. Under our agreement with LG Life Sciences, LG Life Sciences manufactures the API of FACTIVE and is our only source of supply. We use Patheon Inc. (Patheon) to produce the finished FACTIVE tablets and it is currently our only source of FACTIVE tablets. Currently, our only source of supply of bulk capsules of ANTARA is Ethypharm which manufactures the bulk capsules in France and is able to receive ANTARA API from two vendors in Spain and Italy. Further, we have an agreement with Catalent Pharma Solutions, Inc. to package finished ANTARA capsules and FACTIVE tablets.

If Ethypharm, LG Life Sciences, Patheon or Catalent Pharma Solutions experiences any significant difficulties in their respective manufacturing processes for our products, including the API or finished product, we could experience significant interruptions in the supply of ANTARA and FACTIVE. Our inability to coordinate the efforts of our third party manufacturing partners, or the lack of capacity available at our third party manufacturing partners, could impair our ability to supply ANTARA and FACTIVE at required levels. Such an interruption could cause us to incur substantial costs and our ability to generate revenue from ANTARA and FACTIVE may be adversely affected. We may not be able to enter into alternative supply arrangements at commercially acceptable rates, if at all. Also, if we change the source or location of supply or modify the manufacturing process, regulatory authorities will require us to demonstrate that the product manufactured by the new source or from the modified process is equivalent to the product used in any clinical trials that we had conducted. Due to these regulatory requirements, we could incur substantial expenses and/or experience significant interruptions in the supply of ANTARA and FACTIVE if we decided to transfer the manufacture of our products to one or more suppliers in an effort to deal with such difficulties.

As the ANTARA bulk capsules and FACTIVE API are manufactured in France and South Korea, respectively, we must ship our products to the United States for finishing, packaging and labeling, and manufacturing in the case for FACTIVE. While in transit, our API and product, each shipment of which is of significant value, could be lost or damaged. Moreover, at any time after shipment to the United States, our API or finished product could be lost or damaged as our FACTIVE API is stored at Patheon and our ANTARA and FACTIVE finished product is stored at our third party logistics provider, Integrated Commercialization Solutions, Inc. (ICS). Appropriate risk mitigation steps have been taken and insurance is in place. However, depending on when in the process the API or finished product is lost or damaged, we may have limited recourse for recovery against our manufacturers or insurers. As a result, our financial performance could be impacted by any such loss or damage to our API or finished product.

We may also experience interruption or significant delay in the supply of ANTARA and FACTIVE due to natural disasters, acts of war or terrorism, shipping embargoes, labor unrest or political instability in France or South Korea. In any such event, the supply of our products stored at Ethypharm or LG Life Sciences could also be impacted.

---

## **Table of Contents**

Pursuant to our acquisition of worldwide rights to Ramoplanin from Pfizer (formerly Vicuron), we are responsible for the manufacture of both the active pharmaceutical ingredient and finished dosage form of Ramoplanin. Although we plan to seek a partner for Ramoplanin, a contract manufacturer or the partner would be required to produce both the active pharmaceutical ingredient and the final dosage form to support related manufacturing activities. If there is a significant delay in securing a qualified supplier on commercially favorable terms, we could experience a supply shortage of Ramoplanin bulk drug, possibly affecting our ability to consummate partnering arrangements for the commercialization of Ramoplanin.

Moreover, while we may choose to manufacture products in the future, we have no experience in the manufacture of pharmaceutical products for clinical trials or commercial purposes. If we decide to manufacture products, it would be subject to the regulatory requirements described above. In addition, we would require substantial additional capital and would be subject to delays or difficulties encountered in manufacturing pharmaceutical products.

### **We depend on third parties to assist in the management and execution of our product supply chain for ANTARA capsules and FACTIVE tablets.**

We do not have the internal capability to perform product supply chain services including warehousing, inventory management, storage and distribution of commercial and sample quantities of ANTARA capsules and FACTIVE tablets. We have an exclusive arrangement with Integrated Commercialization Solutions, Inc. (ICS) to perform such supply chain services with respect to commercial product through the second quarter of 2010.

We cannot be certain that ICS will be able to perform uninterrupted supply chain services. If ICS were unable to perform their services for any period, we may incur substantial loss of sales to wholesalers and other purchasers of our products. If we are forced to find an alternative supply chain service provider for ANTARA and FACTIVE, in addition to loss of sales, we may also incur costs in establishing a new arrangement.

### **Wholesalers, pharmacies and hospitals may not maintain adequate inventory for the distribution for our products.**

We sell ANTARA and FACTIVE to wholesale drug distributors who generally sell products to retail pharmacies and other institutional customers. We do not promote ANTARA and FACTIVE to these wholesalers, and they do not determine such products prescription demand. However, approximately 90% of our product shipments during the three-month period ended March 31, 2008 was to only three wholesalers. Our ability to commercialize ANTARA and/or FACTIVE will depend, in part, on the extent to which we maintain adequate distribution of ANTARA capsules and FACTIVE tablets via wholesalers, pharmacies and hospitals, as well as other customers. Although a majority of the larger wholesalers and retailers distribute and stock ANTARA and FACTIVE, they may be reluctant to do so in the future if demand is not established. Further, it is possible that wholesalers could decide to change their policies or fees, or both, at some time in the future. This could result in their refusal to distribute smaller volume products, or cause higher product distribution costs, lower margins or the need to find alternative methods of distributing products. Such alternative methods may not exist or may not be economically viable. If we do not maintain adequate distribution of ANTARA capsules or FACTIVE tablets, the commercialization of ANTARA and/or FACTIVE and our anticipated revenues and results of operations could be adversely affected.

### **Under our financing arrangement with Paul Capital, upon the occurrence of certain events, Paul Capital may require us to repurchase the right to receive revenues that we assigned to it or may foreclose on certain assets that secure our obligations to Paul Capital. Any exercise by Paul Capital of its right to cause us to repurchase the assigned right or any foreclosure by Paul Capital could adversely affect our results of operations and our financial condition.**

On August 18, 2006, we and our subsidiary Guardian II Acquisition Corporation, or Guardian II, entered into a revenue interests assignment agreement with Paul Capital pursuant to which we assigned to Paul Capital the right to receive a portion of our net revenues from FACTIVE tablets and Guardian II assigned to Paul Capital the right to receive a portion of its net revenue from ANTARA capsules. To secure its obligations to Paul Capital, Guardian II also granted Paul Capital a security interest in substantially all of its assets, including the U.S. rights to ANTARA.

Under our arrangement with Paul Capital, upon the occurrence of certain events, including if we experience a change of control, undergo certain bankruptcy events of us or our subsidiary, transfer any or substantially all of our rights in ANTARA or FACTIVE, transfer all or substantially all of our assets, breach certain of the covenants, representations or warranties under the revenue interests assignment agreement, or sales of ANTARA are suspended due to an injunction or if we elect to suspend sales of ANTARA as a result of a lawsuit filed by certain third parties, Paul Capital may (i) require us to repurchase the rights we assigned to it at the put/call price in effect on the date such right is exercised or (ii) foreclose on the ANTARA assets that secure our obligations to Paul Capital. Except in the case of certain bankruptcy events, if Paul Capital exercises its right to cause us to repurchase the rights we assigned to it, Paul Capital may not foreclose unless we fail to pay the put/call price as

required.



---

## **Table of Contents**

If Paul Capital were to exercise its right to cause us to repurchase the right we assigned to it, there can be no assurance that we would have sufficient funds available to pay the put/call price in effect at that time. Even if we have sufficient funds available, we may have to use funds that we planned to use for other purposes and our results of operations and financial condition could be adversely affected. If Paul Capital were to foreclose on the ANTARA assets that secure our obligations to Paul Capital, our results of operations and financial condition could also be adversely affected. Paul Capital's right to cause us to repurchase the rights we assigned to it is triggered by, among other things, a change in control, transfer of any of our interests in ANTARA or transfer of all or substantially all of our assets, the existence of that right could discourage us or a potential acquirer from entering into a business transaction that would result in the occurrence of any of those events.

**The development and commercialization of our products may be terminated or delayed, and the costs of development and commercialization may increase, if third parties upon whom we rely to support the development and commercialization of our products do not fulfill their obligations.**

In addition to using third parties to fulfill our manufacturing, distribution and supply chain services, our development and commercialization strategy entails entering into arrangements with corporate collaborators, contract research organizations, licensors, licensees and others to conduct development work, manage our clinical trials and market and sell our products outside of the United States. We do not have the expertise or the resources to conduct such activities on our own and, as a result, we will be particularly dependent on third parties in these areas. For instance, we have entered into exclusive arrangements granting rights to Pfizer, S.A. de C.V, Abbott Laboratories, Ltd. and Menarini International Operation Luxembourg S.A. to develop and sell FACTIVE in Mexico, Canada and Europe, respectively. However, we amended our agreement with Abbott Canada on January 31, 2008, whereby Abbott Canada's development and commercial obligations were substantially reduced.

We may not be able to maintain our existing arrangements with respect to the commercialization of our existing products, ANTARA and FACTIVE, or establish and maintain arrangements or partnerships to develop and commercialize Ramoplanin or any additional product candidates or products we may acquire on terms that are acceptable to us. Any current or future arrangements for development and commercialization may not be successful. If we are not able to establish or maintain agreements relating to our current products, Ramoplanin, our other product candidates or any additional products we may acquire on terms which we deem favorable, our results of operations would be materially adversely affected.

Third parties may not perform their obligations as expected. The amount and timing of resources that third parties devote to developing and commercializing our products are not within our control. Furthermore, our interests may differ from those of third parties that commercialize our products. Disagreements that may arise with these third parties could delay or lead to the termination of the development or commercialization of our product candidates, or result in litigation or arbitration, which would be time consuming and expensive.

If any third party that supports the development or commercialization of our products breaches or terminates its agreement with us, or fails to conduct its activities in a timely and regulatory compliant manner, such breach, termination or failure could:

delay or otherwise adversely impact the development or commercialization of ANTARA capsules, FACTIVE tablets, Ramoplanin, our other product candidates or any additional product candidates that we may acquire or develop;

require us to undertake unforeseen additional responsibilities or devote unforeseen additional resources to the development or commercialization of our products; or

result in the termination of the development or commercialization of our products.

**We bear substantial responsibilities under our license agreements for ANTARA and FACTIVE and our sublicense agreements to Pfizer, S.A. de C.V., Abbott Laboratories, Ltd. and Menarini International Operation Luxembourg S.A., and there can be no assurance that we will successfully fulfill our responsibilities.**

### *ANTARA*

Our exclusive rights to ANTARA are licensed to us by Ethypharm, S.A. (Ethypharm). If we breach the development, license and supply agreement with Ethypharm, it may be entitled to terminate the agreement. Further, in order to maintain our exclusive rights, we must achieve

## Edgar Filing: OSCIENT PHARMACEUTICALS CORP - Form 10-Q

certain minimum annual sales of ANTARA until February 2012 or make payments to Ethypharm to compensate for the difference. Ethypharm also has a right of first refusal on any divestiture of our rights to ANTARA.

We believe that we are currently in compliance with our obligations under the Ethypharm agreement, but there can be no assurance that we will be able to remain in compliance or that we will be able to meet the milestones required for extension of the agreement. As of March 31, 2008, we recorded approximately \$605,000 related to a minimum royalty obligation to Ethypharm. Moreover, Ethypharm's right of first refusal on a divestiture of our rights to ANTARA may adversely affect our ability to effect a change of control or sale of our assets.

**Table of Contents***FACTIVE*

We have an exclusive license from LG Life Sciences to develop and market FACTIVE in North America, France, Germany, the United Kingdom, Luxembourg, Ireland, Italy, Spain, Portugal, Belgium, the Netherlands, Austria, Greece, Sweden, Denmark, Finland, Norway, Iceland, Switzerland, Andorra, Monaco, San Marino, Vatican City, Poland, Czech Republic, Slovakia, Slovenia, Hungary, Estonia, Latvia, Lithuania, Liechtenstein, Malta, Cyprus, Romania, Bulgaria, Croatia, Serbia and Montenegro, Bosnia and Herzegovina, Albania and the Former Yugoslav Republic of Macedonia. Under this agreement, we are responsible, at our expense and through consultation with LG Life Sciences, for the clinical and commercial development of FACTIVE in the countries covered by the license, including the conduct of clinical trials, the filing of drug approval applications with the FDA and other applicable regulatory authorities and the marketing, distribution and sale of FACTIVE in our territory. The agreement with LG Life Sciences also requires that we achieve a minimum gross sales level of \$30 million from our licensed territories over a 12-month period of time starting in approximately the third quarter of 2007 to the third quarter of 2008 which, if not met, LG Life Sciences could elect to terminate the agreement and have the technology be returned to LG Life Sciences. We believe that we are currently in compliance with our obligations under the agreement with LG Life Sciences, but there can be no assurance that we will be able to remain in compliance and meet all of our obligations due to the limitations on our resources and the many risks of conducting clinical trials, as described below in Clinical trials are costly, time consuming and unpredictable, and we have limited experience conducting and managing necessary preclinical and clinical trials for our product candidates and the challenges inherent in the commercialization of new products as described above in Our product candidates will face significant competition in the marketplace.

LG Life Sciences has the obligation under the agreement to diligently maintain its patents and the patents of third parties to which it has rights that, in each case relating to gemifloxacin, the active ingredient in FACTIVE tablets. We have the right, at our expense, to control any litigation relating to suits brought by a third party alleging that the manufacture, use or sale of gemifloxacin in its licensed field in the territories covered by the license infringes upon our rights. We also have the primary right to pursue actions for infringement of any patent licensed from LG Life Sciences under the license agreement within the territories covered by the license. If we elect not to pursue any infringement action, LG Life Sciences has the right to pursue it. The costs of any infringement actions are first paid out of any damages recovered. If we are the plaintiff, the remainder of the damages are retained by us, subject to our royalty obligations to LG Life Sciences. If LG Life Sciences is the plaintiff, the remainder of the damages are divided evenly between us and LG Life Sciences, subject to our royalty obligations to LG Life Sciences. The costs of pursuing any such action could substantially diminish our resources.

In February 2006, we entered into a Sublicensing and Distribution Agreement with Pfizer, S.A. de C.V. (Pfizer Mexico) whereby we sublicensed our rights to commercialize FACTIVE tablets in Mexico to Pfizer Mexico. Under this agreement, we are obligated to exclusively supply all active pharmaceutical ingredient for FACTIVE required by Pfizer Mexico in Mexico. In August 2006, we entered into a Supply, Development and Marketing Agreement with Abbott Laboratories, Ltd. (Abbott Canada), the Canadian affiliate of Abbott. Under this agreement, we are obligated to exclusively supply all finished packaged FACTIVE product required by Abbott Canada. In December 2006, we entered into a License, Supply and Marketing Agreement with Menarini International Operation Luxembourg S.A. (Menarini), whereby we sublicensed our rights to sell FACTIVE tablets in Europe to Menarini. Under the terms of our agreement with Menarini, Menarini is also obligated to exclusively purchase from us, and we must exclusively supply, all API for FACTIVE to be sold in Europe for the earlier to occur of the expiration of the life of certain patents covering the product or expiration of data exclusivity. We believe that, together with our manufacturing partners, we will be able to meet such supply and other obligations under these sublicense and supply agreements but can make no assurances that we will be able to remain in compliance with such responsibilities, which would result in our breach of such agreement.

**Our intellectual property protection and other protections may be inadequate to protect our products.**

Our success will depend, in part, on our ability to obtain commercially valuable patent claims and protect our intellectual property. We currently own or license approximately 57 issued U.S. patents, approximately 56 pending U.S. patent applications, approximately 59 issued foreign patents and approximately 110 pending foreign patent applications. We are not currently involved in any litigation, settlement negotiations, or other legal action regarding patent issues and we are not aware of any patent litigation threatened against us. Our patent position involves complex legal and factual questions, and legal standards relating to the validity and scope of claims in the applicable technology fields are still evolving. Therefore, the degree of future protection for our proprietary rights is uncertain.

Under our Development, License and Supply Agreement with Ethypharm, S.A., we assumed all of the rights and obligations related to the development, manufacturing, marketing and sale of ANTARA in the United States. This license

---

## Table of Contents

includes one issued U.S. patent and several pending patent applications. In conjunction with the financing of our acquisition of ANTARA, we entered into a Security Agreement with Paul Royalty Fund Holdings II, LP, an affiliate of Paul Capital Partners, or Paul Capital, under which our wholly-owned subsidiary granted Paul Capital a security interest in all of its assets, including all rights to ANTARA intellectual property, in order to secure its performance under the financing agreements with Paul Capital. These patents and applications include claims that relate to pharmaceutical compositions containing fenofibrate using the drug delivery technologies incorporated in ANTARA, methods of their use and treatment, and methods of preparing the same. The patent issued to Ethypharm which is listed in the FDA Orange Book is set to expire in 2020.

Under our license agreement with LG Life Sciences, we obtained an exclusive license to develop and market gemifloxacin in certain territories. This license covers 16 issued U.S. patents and a broad portfolio of corresponding foreign patents and pending patent applications. These patents include claims that relate to the chemical composition of FACTIVE, methods of manufacturing and its use for the prophylaxis and treatment of bacterial infections. We have received a Notice of Final Determination from the U.S. Patent and Trademark Office on our patent term extension application for U.S. Patent No. 5,776,944 extending its patent term 659 days to April 4, 2017. The principal U.S. patents for FACTIVE are currently set to expire at various dates, ranging from 2015 to 2019.

On January 8, 2008 the United States Patent and Trademark Office (USPTO) issued us U.S. Patent No. 7,317,001 relating to the treatment of *C. difficile* associated disease (CDAD) using Ramoplanin. We received a patent term adjustment of 565 days thus extending the term through December 20, 2024. In addition to the recently issued patent, we have an additional patent which includes claims relating to methods of manufacturing Ramoplanin. We also have several applications pending relating to additional novel uses of Ramoplanin as well as formulations containing Ramoplanin. The patent covering the chemical composition of Ramoplanin has expired. To provide additional protection for Ramoplanin, we rely on proprietary know-how relating to maximizing yields in the manufacture of Ramoplanin, and intend to rely on the five years of data exclusivity we believe we would receive under the Hatch-Waxman Act in the U.S. and the ten years of market exclusivity in Europe available through the European Medicines Agency (EMA), because Ramoplanin would be a new chemical entity not previously marketed commercially.

We also have the exclusive right to use FACTIVE trademarks, trade names, domain names and logos in conjunction with the use or sale of the product in the territories covered by the license. We acquired exclusive rights to ANTARA trademarks, trade names, domain names and logos. After becoming aware that Antara Biosciences, Inc. filed trademark applications with the USPTO for the ANTARA and ANTARA BIOSCIENCES marks in connection with biotechnology related goods and services we filed a complaint in Federal District Court alleging, among other things, trademark infringement seeking to enjoin ANTARA BIOSCIENCES from using the ANTARA mark. We have reached a settlement with ANTARA BIOSCIENCES whereby they have agreed to abandon their ANTARA trademark applications and cease using the ANTARA marks. Accordingly we have dismissed our complaint before the Federal District Court.

The risks and uncertainties that we will face with respect to our patents and other proprietary rights include the following:

the pending patent applications that we have filed or to which we have exclusive rights may not result in issued patents, may result in issued patents with narrower claims than anticipated or may take longer than expected to result in issued patents;

the claims of any patents which are issued may be limited from those in the patent applications and may not provide meaningful protection;

we may not be able to develop additional proprietary technologies that are patentable;

the patents licensed or issued to us or our partners may not provide a competitive advantage;

other companies may challenge patents licensed or issued to us or our partners;

patents issued to other companies may harm our ability to do business;

the April 30, 2007 U.S. Supreme Court decision in *KSR International Co. vs. Teleflex, Inc.* may raise the standard for patentability for both patent applications and holders, thus making it more difficult to either obtain patents or withstand challenges to patentability based on a determination of obviousness;

other companies may independently develop similar or alternative technologies or duplicate our technologies; and

the patents may be narrow in scope and accordingly other companies may design around technologies we have licensed or developed.

## **Table of Contents**

### **International patent protection is uncertain.**

Patent law outside the United States is uncertain and is currently undergoing review and revision in many countries. Further, the laws of some foreign countries may not protect our intellectual property rights to the same extent as U.S. laws. We may participate in opposition proceedings to determine the validity of our or our competitors' foreign patents, which could result in substantial costs and diversion of our efforts.

### **Our proprietary position may depend on our ability to protect our proprietary confidential information and trade secrets.**

We rely upon certain proprietary confidential information, trademarks, unpatented trade secrets and improvements, unpatented know-how and continuing technological innovation to develop and maintain our competitive position. We generally protect this information with confidentiality agreements that provide that all confidential information developed or made known to others during the course of the employment, consulting or business relationship shall be kept confidential except in specified circumstances. Agreements with employees provide that all inventions conceived by an individual while employed by us are our exclusive property. We cannot guarantee, however, that these agreements will be honored, that we will have adequate remedies for breach if they are not honored or that our proprietary confidential information and trade secrets will not otherwise become known or be independently discovered by competitors.

### **Seasonal fluctuations in demand for FACTIVE may cause our operating results to vary significantly from quarter to quarter.**

We expect demand for FACTIVE to be highest between December 1 and March 31 as the incidence of respiratory tract infections, including CAP and AECB, tends to increase during the winter months. In addition, fluctuations in the duration and severity of the annual respiratory tract infection season may cause our product sales to vary from year to year. Due to these seasonal fluctuations in demand, our results in one quarter may not be indicative of the results for any other quarter or for the entire year.

### **Clinical trials are costly, time consuming and unpredictable, and we have limited experience conducting and managing necessary preclinical and clinical trials for product candidates.**

To obtain FDA approval to market a new drug product or to expand the approved uses of an existing product, we or our partners must demonstrate proof of safety and efficacy in humans. To meet these requirements, we or our partners will have to conduct extensive testing, including potentially preclinical testing and adequate and well-controlled clinical trials. Conducting clinical trials is a lengthy, time-consuming and expensive process. The length of time required to conduct required studies may vary substantially according to the type, complexity, novelty and intended use of the product candidate, and often can be several years or more per trial. Delays associated with products for which clinical trials are required may cause us to incur additional operating expenses.

The Phase II trial for our product candidate, Ramoplanin, to assess the safety and efficacy of treating *Clostridium difficile*-associated disease, or CDAD, was completed in 2004 but did not meet its primary endpoint. Prior clinical and preclinical trials for Ramoplanin were conducted by Vicuron and its licensees, from whom we acquired rights to Ramoplanin. Although we have agreed with the FDA to a Special Protocol Assessment regarding specific components of a Phase III program that, if completed successfully, would support regulatory approval for the indication, we can give no assurance that as clinical trials proceed or as part of an NDA review process, if any, the FDA will not determine that a previously approved Special Protocol Assessment for a particular protocol is no longer valid. Additionally, in October 2007, the FDA issued draft guidance on the use of non-inferiority studies to support approval of antibiotics. Under this draft guidance, the FDA recommends that for some antibiotic indications, sponsor companies carefully consider study designs other than non-inferiority, such as placebo-controlled trials demonstrating the superiority of a drug candidate to placebo. While the indications identified by the FDA in the draft guidance are not indications which we are currently pursuing, the draft guidance does not articulate clear standards or policies for demonstrating the safety and efficacy of antibiotics generally. The lack of clear guidance from the FDA creates uncertainties about the standards for the approval of antibiotics could delay or ultimately prevent commercialization of new antibiotic product candidates such as Ramoplanin or additional indications for FACTIVE. If the trials or the filings are delayed or not approved by the FDA, our business may be adversely affected.

If we choose to pursue additional indications or expand the label for ANTARA or FACTIVE, or are required to conduct additional clinical trials, we may not be able to demonstrate the safety and efficacy of FACTIVE or ANTARA for those indications to the satisfaction of the FDA, or other regulatory authorities. We may also be required to demonstrate that our proposed products represent an improved form of treatment over existing therapies and we may be unable to do so without conducting further clinical studies. Negative, inconclusive or inconsistent clinical trial results could prevent regulatory approval, increase the cost and timing of regulatory approval or require additional studies or a filing for a narrower indication or label expansion.



## **Table of Contents**

In addition, the cost of human clinical trials varies dramatically based on a number of factors, including the order and timing of clinical indications pursued, the extent of development and financial support from alliance partners, the number of patients required for enrollment, the difficulty of obtaining clinical supplies of the product candidate, and the difficulty in obtaining sufficient patient populations and clinicians.

We have limited experience in conducting and managing the preclinical and clinical trials necessary to obtain regulatory marketing approvals. We may not be able to obtain the approvals necessary to conduct clinical studies. Also, the results of our clinical trials may not be consistent with the results obtained in preclinical studies or the results obtained in later phases of clinical trials may not be consistent with those obtained in earlier phases. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after experiencing promising results in early animal and human testing.

Even if a product gains regulatory approval, the product and the manufacturer of the product will be subject to continuing regulatory review, including the requirement to conduct post-approval clinical studies. We may be restricted or prohibited from marketing or manufacturing a product, even after obtaining product approval, if previously unknown problems with the product or its manufacture are subsequently discovered.

### **We could experience delays in clinical development which could delay anticipated product launches.**

The speed with which we are able to complete clinical trials for future product candidates, when and if we, or any third party with whom we partner, elects to commence Phase III development of Ramoplanin, and our applications for marketing approval will depend on several factors, including the following:

the rate of patient enrollment, which is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study and the nature of the protocol;

fluctuations in the disease incidence for patients available to enroll in our trials;

compliance of patients and investigators with the protocol and applicable regulations;

prior regulatory agency review and approval of our applications and procedures;

analysis of data obtained from preclinical and clinical activities which are susceptible to varying interpretations, which interpretations could delay, limit or prevent regulatory approval;

changes in the policies of regulatory authorities for drug approval during the period of product development including the FDA's recent draft guidance released in October 2007 relating to Antibacterial Drug Products: Use of Noninferiority Studies to Support Approval; and

the availability of skilled and experienced staff to conduct and monitor clinical studies, to accurately collect data and to prepare the appropriate regulatory applications.

### **We depend on key personnel, including members of our direct sales force, in a highly competitive market for such skilled personnel.**

We are highly dependent on the principal members of our senior management and key scientific, sales and technical personnel. The loss of any of our personnel could have a material adverse effect on our ability to achieve our goals. We currently maintain employment agreements with the following executive officers: Steven M. Rauscher, President and Chief Executive Officer; Dominick Colangelo, Esq., Executive Vice President, Corporate Development and Operations; and Philippe M. Maitre, Executive Vice President and Chief Financial Officer. The term of each employment agreement continues until it is terminated by the officer or Oscient.



## Edgar Filing: OSCIENT PHARMACEUTICALS CORP - Form 10-Q

Our future success is dependent upon our ability to attract and retain additional qualified sales and marketing, clinical development, scientific and managerial personnel. Like others in our industry, we may face, and in the past we have faced from time to time, difficulties in attracting and retaining certain employees with the requisite expertise and qualifications. We believe that our historical recruiting periods and employee turnover rates are similar to those of others in our industry; however, we cannot be certain that we will not encounter greater difficulties in the future.

With routine employee turnover, we also face the risk of being unable to enforce our rights under non-compete and non-solicitation provisions as well as confidentiality obligations that protect the Company. We also need to guard against the same obligations that our employees or our potential employees have with their former employers.

---

## **Table of Contents**

**Changes in the expensing of stock-based compensation have resulted and will continue to result in unfavorable accounting charges and may require us to change our compensation practices. Any change in our compensation practices may adversely affect our ability to attract and retain qualified scientific, technical and business personnel.**

We rely on stock options to compensate existing employees and attract new employees. As a result of new accounting rules implemented by the Financial Accounting Standards Board, as of January 1, 2006, we were required to record the expense for the fair value of stock options granted to employees and the fair value of purchase rights under our employee stock purchase plan, thereby increasing our operating expenses and reported losses. Although we intend to continue to include various forms of equity in our compensation plans, if the extent to which we use forms of equity in our plans is reduced due to the negative effect on earnings, it may be difficult for us to attract and retain qualified scientific, technical and business personnel.

**Failure to obtain or maintain regulatory approvals in foreign jurisdictions will prevent us from marketing FACTIVE abroad.**

We have entered into commercialization relationships with Pfizer Mexico, Abbott Canada and Menarini whereby we sublicensed our rights to sell FACTIVE tablets in Mexico to Pfizer Mexico, in Canada to Abbott Canada and in Europe to Menarini. Obtaining foreign approvals may require additional trials and expense. Further, in order to market FACTIVE in Europe, we or our distribution partners may need to obtain multiple regulatory approvals. For instance, our predecessor's original regulatory filing in the United Kingdom was rejected. We may not be able to obtain approval or may be delayed in obtaining approval from any or all of the jurisdictions in which we seek approval to market FACTIVE. Further, based on the amendment of our agreement with Abbott Canada of January 31, 2008, Abbott Canada is no longer obligated to pursue the CAP and ABS indications in Canada. If our partners are unsuccessful in their efforts to obtain and/or expand their respective marketing approvals, the revenues that we expect to obtain from the sales of FACTIVE could be significantly limited.

**We rely on operational data obtained from third party vendors which could be inaccurate.**

We rely on prescription and wholesaler data obtained from industry-accepted, third-party data sources. These third-party data projections may not accurately reflect actual prescriptions or trade levels of inventory. If this data turns out to be inaccurate or unreliable and our controls are not effective, there could be an adverse effect on our ability to properly manage inventory and our financial performance.

## **RISKS RELATED TO OUR INDUSTRY**

**Health care insurers, the government and other payers may not pay for our products or may impose limits on reimbursement.**

Our ability to commercialize ANTARA capsules, FACTIVE tablets, Ramoplanin and our future products will depend, in part, on the extent to which reimbursement for such products will be available from third-party payers, such as Medicare, Medicaid, health maintenance organizations, health insurers and other public and private payers. We cannot assure you that third-party payers will pay for such products or will establish and maintain price levels sufficient for realization of an appropriate return on our investment in product development. If adequate coverage and reimbursement levels are not provided by government and private payers for use of our products, our products may fail to achieve market acceptance and our results of operations may be materially adversely affected. Under the Medicare Part D outpatient prescription drug benefit, Medicare beneficiaries (primarily the elderly over 65 and the disabled) may enroll in private drug plans. There are multiple types of Part D plans and numerous plan sponsors, each with its own formulary and product access requirements. The plans have considerable discretion in establishing formularies and tiered co-pay structures and in placing prior authorization and other restrictions on the utilization of specific products. In addition, Part D plan sponsors are permitted and encouraged to negotiate rebates with manufacturers. The profitability of our products may depend on the extent to which they enjoy preferred status on the formularies of a significant portion of the largest Part D prescription drug plans. Our ability to obtain such preferred status on favorable economic terms cannot be assured. Additionally, the Part D program has been the subject of much controversy since its inception in 2003, and significant amendments, including an amendment to authorize the Federal Government to directly negotiate drug prices with manufacturers, are possible. Such amendments could adversely affect our anticipated revenues and results of operations, possibly materially.

Most state Medicaid programs have established preferred drug lists, or PDLs, and the process, criteria and timeframe for obtaining placement on the PDL varies from state to state. Under the Medicaid drug rebate program, a manufacturer must pay a rebate for Medicaid utilization of a product. The rebate is based on the greater of (i) a specified percentage of the product's average manufacturer price (AMP) or (ii) the difference between the product's AMP and the best price offered by the manufacturer. In addition, many states have established supplemental rebate programs as a condition for including a drug product on a PDL. The profitability of our products may depend on the extent to which they appear on the PDLs of a significant number of state Medicaid programs and the amount of the rebates that must be paid to such states. In addition,



## **Table of Contents**

there is significant fiscal pressure on the Medicaid program, and amendments to lower the pharmaceutical costs of the program are possible. Such amendments could adversely affect our anticipated revenues and results of operations, possibly materially.

Many health maintenance organizations and other third-party payers use formularies, or lists of drugs for which coverage is provided under a health care benefit plan, to control the costs of prescription drugs. Each payer that maintains a drug formulary makes its own determination as to whether a new drug will be added to the formulary and whether particular drugs in a therapeutic class will have preferred status over other drugs in the same class. This determination often involves an assessment of the clinical appropriateness of the drug and sometimes the cost of the drug in comparison to alternative products. We cannot assure you that ANTARA capsules, FACTIVE tablets, Ramoplanin or any of our future products will be added to payers' formularies, whether our products will have preferred status to alternative therapies, nor whether the formulary decisions will be conducted in a timely manner. We may also decide to enter into discount or formulary fee arrangements with payers, which could result in our receiving lower or discounted prices for our products.

### **Wholesalers, pharmacies and hospitals may not provide adequate distribution for our products.**

Our ability to commercialize our products will depend, in part, on the extent to which we obtain adequate distribution of our products via wholesalers, pharmacies and hospitals, as well as other customers. Wholesalers and larger retailers may be reluctant to stock and distribute Oscient products since we are not a large, well-established company. If we do not obtain adequate distribution of our products, the commercialization of ANTARA and FACTIVE and our anticipated revenues and results of operations could be adversely affected.

### **If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, we could be forced to pay substantial damage awards.**

The use of any of our product candidates in clinical trials, and the sale of any approved products, might expose us to product liability claims. We currently maintain, and we expect that we will continue to maintain, product liability insurance coverage in the amount of \$10.0 million per occurrence and \$10.0 million in the aggregate. Such insurance coverage might not protect us against all of the claims to which we might become subject. We might not be able to maintain adequate insurance coverage at a reasonable cost or in sufficient amounts or scope to protect us against potential losses. In the event a claim is brought against us, we might be required to pay legal and other expenses to defend the claim, as well as uncovered damage awards resulting from a claim brought successfully against us. Furthermore, whether or not we are ultimately successful in defending any such claims, we might be required to direct financial and managerial resources to such defense and adverse publicity could result, all of which could harm our business.

In addition, a product recall or excessive warranty claims (in any such case, whether arising from manufacturing deficiencies, labeling errors or other safety or regulatory reasons) could have an adverse effect on our product sales or require a change in the indications for which our products may be used.

## **RISKS RELATED TO THE SECURITIES MARKET**

### **Our stock price is highly volatile.**

The market price of our stock has been and is likely to continue to be highly volatile due to the risks and uncertainties described herein, as well as other factors, including:

our ability to successfully commercialize ANTARA capsules and FACTIVE tablets;

the revenues that we may derive from the sale of ANTARA capsules and FACTIVE tablets, as compared to analyst estimates or to our own guidance;

our ability to enter into transactions to acquire, license or co-promote additional products;

## Edgar Filing: OSCIENT PHARMACEUTICALS CORP - Form 10-Q

the results of any clinical trials that we may conduct and the pace of our progress in those clinical trials;

the results of clinical trials conducted by partners for Ramoplanin or products developed from any of our legacy alliances and the pace of progress in those clinical trials;

whether we will be able to successfully integrate any additional products that we acquire, license or co-promote into our sales and marketing efforts;

the timing of the achievement of development milestones and other payments under our strategic alliance agreements;

termination of, or an adverse development in, our strategic alliances;

conditions and publicity regarding the pharmaceutical industry generally;

## **Table of Contents**

price and volume fluctuations in the stock market at large which do not relate to our operating performance;

variations in our rates of product returns, allowances and rebates and discounts;

sales of shares of our common stock in the public market; and

comments by securities analysts, or our failure to meet market expectations, including our projected financial performance.

Over the two-year period ending March 31, 2008 the closing price of our common stock as reported on The NASDAQ Global Market ranged from a high of \$15.60 to a low of \$1.10. The stock market has from time to time experienced extreme price and volume fluctuations that are unrelated to the operating performance of particular companies. In the past, companies that have experienced volatility have sometimes been the subject of securities class action litigation. If litigation were instituted on this basis, it could result in substantial costs and a diversion of management's attention and resources. These broad market fluctuations may adversely affect the price of our securities, regardless of our operating performance.

### **Failure to satisfy The NASDAQ Global Market continued listing requirements may result in our common stock being delisted from The NASDAQ Global Market.**

Our common stock is currently listed on The NASDAQ Global Market under the symbol "OSCI". In the event that we fail to satisfy any of the listing requirements, our common stock may be put under review or removed from listing on The NASDAQ Global Market.

For example, on August 17, 2007, we were notified by NASDAQ that our common stock was subject to delisting from The NASDAQ Global Market based upon our failure to satisfy the \$50 million market value of listed securities requirement for the previous ten consecutive trading days (pursuant to Rule 4450(b)(1)(A) of the NASDAQ Marketplace Rules). We requested a hearing before the NASDAQ Listing Qualifications Panel (the "NASDAQ Panel") and on November 8, 2007, we presented our plan to evidence compliance. The NASDAQ Panel granted our request for continued listing of our securities on The NASDAQ Global Market and on February 7, 2008 we announced that the Company received a determination from The NASDAQ Stock Market indicating that the Company had evidenced full compliance with the requirements for continued listing on The NASDAQ Global Market and that accordingly, the Company's securities continue to trade on The NASDAQ Global Market.

If we are unable to comply with The NASDAQ Global Market listing requirements in the future, our common stock may be delisted from The NASDAQ Global Market. In the event that we are delisted from The NASDAQ Global Market, we may not be able to meet the requirements necessary for the transfer to or listing on another national exchange, including The NASDAQ Capital Market.

### **Multiple factors beyond our control may cause fluctuations in our operating results and may cause our business to suffer.**

Our revenues and results of operations may fluctuate significantly, depending on a variety of factors, including the following:

the pace of our commercialization of ANTARA capsules and FACTIVE tablets, and in the case of FACTIVE, seasonal fluctuations in the duration and severity of the annual respiratory tract infection season;

the level of acceptance by physicians and third party payers of ANTARA and FACTIVE;

the progress of any future clinical trials for our products;

the progress of any clinical trials conducted by partners for Ramoplanin or products developed through our legacy alliances;

## Edgar Filing: OSCIENT PHARMACEUTICALS CORP - Form 10-Q

our success in concluding transactions to acquire additional approved products and product candidates, and the pace of our commercialization of such additional products;

the introduction of new products and services by our competitors;

regulatory actions; and

expenses related to, and the results of, litigation and other proceedings relating to intellectual property rights.

We will not be able to control many of these factors. In addition, if our revenues in a particular period do not meet expectations, we may not be able to adjust our expenditures in that period, which could cause our business to suffer. We believe that period-to-period comparisons of our financial results will not necessarily be meaningful. You should not rely on these comparisons as an indication of our future performance. If our operating results in any future period fall below the expectations of securities analysts and investors, our stock price may fall, possibly by a significant amount.

**Table of Contents**

**ITEM 2: UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

None

**ITEM 3: DEFAULTS UPON SENIOR SECURITIES**

None

**ITEM 4: SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

None

**ITEM 5: OTHER INFORMATION**

None

**ITEM 6: EXHIBITS**

**Description**

31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act.

31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act.

32.1 Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act.

32.2 Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act.

*The following Oscient-owned or licensed trademarks are used in this Quarterly Report on Form 10-Q: Oscient, Oscient Pharmaceuticals, ANTARA® and FACTIVE®. All are covered by registrations or pending applications for registration in the U.S. Patent and Trademark Office and other countries. Other trademarks used in this Quarterly Report on Form 10-Q are the property of their respective owners.*



**Table of Contents**

**SIGNATURE**

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 who also serves in the capacity of principal financial officer.

Oscient Pharmaceuticals Corporation

/s/ PHILIPPE M. MAITRE

**Philippe M. Maitre**  
**Executive Vice President & Chief Financial Officer**  
**(Principal Financial Officer)**

May 9, 2008

**Table of Contents**

**OSCIENT PHARMACEUTICALS CORPORATION**

**EXHIBIT INDEX**

**Description**

- 31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act.
- 31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act.
- 32.1 Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act.
- 32.2 Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act.