

OSCIENT PHARMACEUTICALS CORP

Form 10-Q

November 09, 2006

Table of Contents

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**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

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**FORM 10-Q**

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

For the Quarterly Period Ended: September 30, 2006

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

Commission File No: 0-10824

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**OSCIENT PHARMACEUTICALS CORPORATION**

(Exact name of registrant as specified in its charter)

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**MASSACHUSETTS**  
(State or other jurisdiction of

incorporation or organization)

**1000 WINTER STREET, SUITE 2200**

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

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

**04-2297484**  
(I.R.S. Employer

Identification no.)

**02451**  
(Zip code)

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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

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

Large accelerated filer  Accelerated filer  Non-accelerated filer

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

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

**COMMON STOCK**  
**\$.10 PAR VALUE**

**108,417,701 Shares**  
**Outstanding November 6, 2006**

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**Table of Contents**

**OSCIENT PHARMACEUTICALS CORPORATION**

**INDEX TO FINANCIAL INFORMATION AND OTHER INFORMATION**

	<b>Page</b>
Part I Financial Information (unaudited):	
<u>Consolidated Balance Sheets as of September 30, 2006 and December 31, 2005</u>	3
<u>Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2006 and 2005</u>	4
<u>Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2006 and 2005</u>	5
<u>Notes to Consolidated Financial Statements</u>	6
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	23
<u>Quantitative and Qualitative Disclosures about Market Risk</u>	37
<u>Controls and Procedures</u>	37
Part II Other Information:	
<u>Legal Proceedings</u>	38
<u>Risk Factors</u>	38
<u>Submission of Matters to a Vote of Security Holders</u>	51
<u>Exhibits</u>	51
<u>Signature</u>	52
<u>Exhibit Index</u>	53

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

	September 30, 2006 (unaudited)	December 31, 2005
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 42,770	\$ 65,618
Marketable securities (held-to-maturity)		2,696
Restricted cash	5,346	5,386
Interest receivable	225	461
Notes receivable	597	561
Accounts receivable (net of allowance for bad debts of \$344 and \$0 in 2006 and 2005, respectively)	9,218	6,206
Inventories	14,901	14,187
Prepaid expenses and other current assets	3,019	4,340
<b>Total current assets</b>	<b>76,076</b>	<b>99,455</b>
Property and Equipment, at cost:		
Manufacturing and computer equipment	4,494	4,622
Equipment and furniture	1,160	1,160
Leasehold improvements	135	135
	5,789	5,917
Less Accumulated depreciation	4,348	4,069
	1,441	1,848
Restricted cash	3,919	6,344
Long-term notes receivable	1,432	1,739
Other assets	4,242	4,573
Intangible assets, net	122,407	65,607
Goodwill	78,142	61,529
	\$ 287,659	\$ 241,095
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 7,735	\$ 6,447
Accrued expenses and other current liabilities	13,283	10,163
Current portion of accrued facilities impairment charge	3,012	2,175
Accrued restructuring charge	172	1,076
Clinical trial expense accrual	1,409	1,844
Deferred revenue	444	
<b>Total current liabilities</b>	<b>26,055</b>	<b>21,705</b>
Long-term liabilities:		
Long-term obligations, net of current maturities	195,060	175,060

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Revenue interest liability	40,000	
Noncurrent portion of accrued facilities impairment charge	11,506	14,029
Other long-term liabilities	3,271	2,200
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>SHAREHOLDERS' EQUITY:</b>		
Series B restricted common stock, \$0.10 par value - Authorized - 625 shares, Issued and Outstanding - None		
Common stock, \$0.10 par value - Authorized - 174,375 shares, Issued and Outstanding - 108,409 and 76,688 in 2006 and 2005, respectively	10,841	7,735
Additional paid-in-capital	402,303	357,968
Accumulated deficit	(401,214)	(337,428)
Deferred compensation		(11)
Note receivable from officer	(163)	(163)
<b>Total shareholders' equity</b>	<b>11,767</b>	<b>28,101</b>
	\$ 287,659	\$ 241,095

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 September 30, 2006	Three Months Ended September 30, 2005	Nine Months Ended September 30, 2006	Nine Months Ended September 30, 2005
<b>Revenues:</b>				
Product Sales	\$ 8,308	\$ 4,778	\$ 20,176	\$ 12,495
Co-promotion	3,474	1,161	6,890	1,531
Biopharmaceutical		2	143	96
Other Revenues	580		679	
<b>Total revenues</b>	<b>12,362</b>	<b>5,941</b>	<b>27,888</b>	<b>14,122</b>
<b>Costs and expenses:</b>				
Cost of product sales (1)	6,573	2,018	11,808	6,391
Research and development (1)	4,281	2,814	10,415	13,009
Selling and marketing (1)	17,215	19,460	54,897	57,278
General and administrative (1)	4,379	2,524	11,781	10,150
<b>Total costs and expenses</b>	<b>32,448</b>	<b>26,816</b>	<b>88,901</b>	<b>86,828</b>
<b>Loss from operations</b>	<b>(20,086)</b>	<b>(20,875)</b>	<b>(61,013)</b>	<b>(72,706)</b>
<b>Other income (expense):</b>				
Interest income	842	877	2,439	2,628
Interest expense	(2,807)	(2,055)	(6,889)	(6,196)
Gain (loss) on sale of fixed assets	(1)	8	1	51
Income from sale of intellectual property				2,500
Gain on disposition of investment	1,380	143	1,617	2,162
Other Income	15		58	43
<b>Net other income (expense)</b>	<b>(571)</b>	<b>(1,027)</b>	<b>(2,774)</b>	<b>1,188</b>
<b>Loss from continuing operations</b>	<b>(20,657)</b>	<b>(21,902)</b>	<b>(63,786)</b>	<b>(71,518)</b>
<b>Income from discontinued operations</b>				<b>35</b>
<b>Net loss</b>	<b>\$ (20,657)</b>	<b>\$ (21,902)</b>	<b>\$ (63,786)</b>	<b>\$ (71,483)</b>
<b>Loss from continuing operations per common share:</b>				
Basic and diluted	\$ (0.20)	\$ (0.29)	\$ (0.70)	\$ (0.94)
<b>Net loss per common share:</b>				
Basic and diluted	\$ (0.20)	\$ (0.29)	\$ (0.70)	\$ (0.94)
<b>Weighted average common shares outstanding:</b>				
Basic and diluted	101,936	76,759	91,201	76,341
<b>(1) Includes non-cash stock-based compensation as follows:</b>				
Cost of product sales	30		63	
Research and development	23		115	836
Selling and marketing	348		1,052	

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General and Administrative	620	6	1,881	163
	\$ 1,021	\$ 6	\$ 3,110	\$ 999

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)

	Nine Months Ended September 30, 2006	Nine Months Ended September 30, 2005
<b>Cash Flows from Operating Activities:</b>		
Loss from continuing operations	\$ (63,786)	\$ (71,517)
Adjustments to reconcile net loss from continuing operations to net cash used in operating activities:		
Depreciation and amortization	4,664	4,035
Provision for excess and obsolete inventories	986	
Provision for bad debts	344	
Non-cash interest expense	1,095	1,294
Gain on disposal of fixed assets		(51)
Gain on disposition of investment	(1,617)	(2,163)
Stock based compensation	3,110	1,000
Changes in assets and liabilities:		
Interest receivable	236	982
Accounts receivable	(3,356)	409
Inventories	(1,700)	(5,629)
Prepaid expenses and other current assets	1,321	5,203
Accounts payable	1,288	(4,432)
Accrued expenses and other liabilities	3,120	(5,517)
Clinical trial expense accrual	(435)	1,432
Deferred revenue	444	(1,302)
Accrued facilities impairment charge	(2,167)	(2,378)
Accrued restructuring charge	(904)	(907)
Accrued other long-term liabilities	1,071	905
Net cash used in operating activities	(56,286)	(78,636)
<b>Cash Flows from Investing Activities:</b>		
Proceeds from maturities of marketable securities	2,696	83,489
Proceeds from disposition of investment	1,617	2,388
Purchases of property and equipment	(158)	(1,051)
Proceeds from sale of property and equipment	1	225
Decrease in restricted cash	2,465	2,587
Increase in other assets	(284)	(49)
Proceeds from notes receivable	271	267
Issuance of note receivable		(2,740)
Cash paid for acquisition of ANTARA	(77,513)	
Net cash (used in) provided by investing activities	(70,905)	85,116
<b>Cash Flows from Financing Activities:</b>		
Net proceeds from issuance of stock in connection with acquisition of ANTARA	9,958	
Proceeds from exercise of stock options	166	546
Proceeds from issuance of stock under the employee stock purchase plan	740	417
Proceeds from issuance of term note	20,000	
Proceeds from assignment of revenue interest	40,000	
Proceeds from financing, net of issuance costs	33,478	
Payments on long-term obligations		(292)
Net cash provided by financing activities	104,342	671



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**Cash Flows from Discontinued Operations:**

Operating cash flows		35
Total		35
<b>Net (Decrease) Increase in Cash and Cash Equivalents</b>	(22,848)	7,186
<b>Cash and Cash Equivalents, beginning of period</b>	65,618	64,743
<b>Cash and Cash Equivalents, end of period</b>	\$ 42,770	\$ 71,929

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) Basis of Presentation**

These consolidated financial statements have been prepared by Oscient Pharmaceuticals Corporation (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, 2005 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 March 10, 2006.

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

The Company is a commercial-stage biopharmaceutical company marketing two FDA-approved products with its national primary care sales force a fluoroquinolone antibiotic, FACTIVE® (gemifloxacin mesylate) tablets, and a cardiovascular product, ANTARA® 130 mg and ANTARA® 43 mg (fenofibrate) capsules. 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. FACTIVE was launched in the U.S. market in September 2004. ANTARA is approved by the U.S. Food and Drug Administration to treat hypercholesterolemia (high blood cholesterol) and hypertriglyceridemia (high triglycerides) in combination with a healthy diet. The Company began promoting ANTARA with its national sales force in late August 2006. The Company licenses the rights to ANTARA from Ethypharm S.A of France. Additionally, the Company has a novel, late-stage antibiotic candidate, Ramoplanin, under investigation for the treatment of *Clostridium difficile*-associated disease and has begun exploring partnering and other strategic opportunities for the continued development of Ramoplanin.

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.

**(a) Revenue Recognition**

The Company's principal source of revenue is the sale of FACTIVE tablets and ANTARA capsules. In the second quarter of 2005, the Company began recognizing co-promotion revenue in connection with its co-promotion agreement with Auxilium Pharmaceuticals, Inc. (Auxilium), which terminated on August 31, 2006. Other historical sources of revenue include biopharmaceutical alliances and royalties from the divested genomic services business. In future periods, the Company expects its revenues derived from biopharmaceutical alliances will continue to decrease but expects that product revenues will continue to increase based on anticipated increased volume of prescriptions of FACTIVE tablets and ANTARA capsules.

Although ANTARA revenue results should be consistent throughout the fiscal year, the Company expects demand for FACTIVE to be highest from November 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 its 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 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

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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. Also, the cost of FACTIVE and ANTARA associated with amounts recorded as deferred revenue is recorded in inventory until such time as risk of loss has passed.

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**Table of Contents***Co-Promotion Revenue*

Amounts earned under the Company's co-promotion agreement with Auxilium from the sale of TESTIM<sup>®</sup> gel, a product developed by Auxilium, are classified as co-promotion revenue in the accompanying consolidated statements of operations. Auxilium is obligated to pay the Company a co-promotion fee based on a specified percentage of the gross profit from TESTIM sales attributable to primary care physicians in the U.S. that exceeds a specified cumulative sales threshold, determined on an annual basis. The specific percentage is based upon TESTIM sales levels attributable to primary care physicians in the U.S. and the marketing expenses incurred by the Company in connection with the promotion of TESTIM under the co-promotion agreement. Such co-promotion revenue is earned when TESTIM units are dispensed through patient prescriptions. The arrangement contains a clause that provides Auxilium the ability to recover revenue if specified cumulative sales thresholds are not met. There is no cost of goods sold associated with co-promotion revenue, and the selling and marketing expenses incurred with respect to the co-promotion arrangement are classified as selling and marketing expenses in the accompanying consolidated statements of operations. On August 31, 2006, the Company and Auxilium mutually agreed to conclude this co-promotion arrangement and agreed to share profits from primary care sales, as provided for under the Co-Promotion Agreement, through August 31, 2006. As part of the termination of the Co-Promotion Agreement, the Company received \$1,800,000 from Auxilium as additional compensation for commercialization efforts by its sales force through August 31, 2006, which has been recognized as revenue in the quarter ended September 30, 2006.

*Biopharmaceutical/Other Revenue*

Prior to the merger with GeneSoft Pharmaceuticals, Inc. in 2004, the Company pursued biopharmaceutical revenues through alliance partnerships with pharmaceutical companies and through government grants. Biopharmaceutical revenues have consisted of government research grants and license fees, contract research and milestone payments from alliances with pharmaceutical companies. The Company also maintained a genomics services business. The Company has now shifted its focus to the development and commercialization of pharmaceutical products. The declining revenues and associated expenses for the genomics services business have been classified as discontinued operations in the accompanying consolidated financial statements.

Other revenues consist of sublicensing arrangements related to FACTIVE. The Company recognizes revenue in accordance with SAB No. 104 and Emerging Issues Task Force Issue (EITF) No. 00-21, "Revenue Arrangements with Multiple Deliverables" (EITF No. 00-21). In accordance with EITF No. 00-21, the up-front license payment related to the Pfizer Mexico license agreement will be recognized as revenue over the term of the Company's continuing obligations, which is eighteen months. In addition, 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 during the three and nine months ended September 30, 2006.

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

The Company's sales of FACTIVE and ANTARA 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 FACTIVE and ANTARA 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, return rates for similar competitive products that have a similar shelf life and are sold in the same distribution channel, the remaining time to 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 six months subsequent to the expiration date of the Company's product. Each of FACTIVE tablets and ANTARA capsules have a 36-month expiration period from the date of manufacturing. At September 30, 2006 and December 31, 2005, the Company's product return reserve was approximately \$573,000 and \$720,000, 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.

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**Table of Contents***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 will deduct the 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 September 30, 2006 and December 31, 2005, the balance of the cash discounts reserve was approximately \$111,000 and \$50,000, respectively.

*Rebates*

The liability for managed care and Medicaid rebates is calculated based on historical and current rebate redemption and utilization rates contractually submitted by each state. As of September 30, 2006 and December 31, 2005, the balance of the accrual for managed care and Medicaid rebates was approximately \$975,000 and \$381,000, respectively. Considering the estimates made by the Company, as well as estimates prepared by third party utilization reports that are used in evaluating the required liability balance, the Company believes its estimates are reasonable. As of September 30, 2006, the significant change to the Company's estimates for managed care and Medicaid rebates in the periods presented is primarily attributable to the acquisition of the ANTARA product line.

*Special Promotional Programs:*

The Company has, from time to time, offered certain promotional incentives to its customers for both FACTIVE and ANTARA and may continue this practice in the future. Such programs include: sample cards to end consumers, certain product incentives to pharmacy customers, and other sales stocking allowances. Examples of programs utilized to date follow:

*Sample Card Programs for FACTIVE*

During the second quarter of 2006, the Company initiated two sample card programs whereby the Company offered an incentive to patients in the form of a free full-course sample card for FACTIVE. The Company has accounted for these programs in accordance with EITF No. 01-09, *Accounting for Consideration Given by a Vendor to a Customer* (EITF No. 01-09). For the first sample card program, the Company was able to develop a reasonable and reliable estimate of the amount of expected reimbursement claims based on actual claims submitted by and processed by a third party claims processing organization. For the second sample card program, the estimate of expected reimbursement claims was based on the historical actual reimbursement claims for similar completed programs that the Company conducted in the first and second quarters of 2006. The first program expired on June 15, 2006 and the second program expired on September 30, 2006. The balance of the liability at September 30, 2006 for these sample card programs was approximately \$256,000.

*Voucher Rebate Program for FACTIVE*

During the second and third quarters of 2006, the Company initiated three voucher rebate programs whereby it offered mail-in rebates to retail consumers. The Company has accounted for these programs in accordance with EITF No. 01-09. The liabilities the Company recorded for these voucher rebate programs were estimated based upon the historical rebate redemption rates for similar completed programs that the Company commenced in the first quarter of 2005, fourth quarter of 2005, and first quarter of 2006. The first program expired on June 30, 2006, the second program expired on August 31, 2006, and the third program expired on September 30, 2006. As of September 30, 2006 and December 31, 2005, the balance of the liabilities for these voucher programs totaled approximately \$262,000 and \$105,000, respectively.

*Voucher Rebate Program for ANTARA*

During the third quarter of 2006, the Company initiated a voucher rebate program whereby it offered a point-of-sale rebate to retail consumers. The Company has accounted for this program in accordance with EITF No. 01-09. The liability the Company recorded for this voucher rebate program was estimated based upon the historical rebate redemption rates for similar completed programs by other pharmaceutical companies. This program expires on December 31, 2006. As of September 30, 2006, the balance of the liability for this voucher program totaled approximately \$339,000.

**(c) Clinical Trial Expense Accrual**

The Company's clinical development trials related to FACTIVE are primarily performed by outside parties. At the end of each accounting period, the Company estimates both the total cost and time period of the trials and the percent completed as of that accounting date. The Company also adjusts these estimates when final invoices are received. For the nine months ended September 30, 2006 and the year ended December 31, 2005, the Company adjusted its accrual for clinical trial expenditures to reflect its most current estimate of liabilities outstanding to third parties.

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However, the possibility exists that the timing or cost of the clinical trials might be longer or shorter and cost more or less than estimated and that the associated financial adjustments would be reflected in future periods.

**Table of Contents**

As a condition to the approval to sell FACTIVE tablets, the U.S. Food and Drug Administration (FDA) has required, as a post-marketing study commitment, that the Company conduct a prospective, randomized study, called the FORCE trial, comparing FACTIVE tablets (5,000 patients) to 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 includes patients of different ethnicities to gain safety information in populations not substantially represented in the existing clinical trial program. This FDA-approved Phase IV trial commenced patient enrollment in the fall of 2004 and is scheduled to be completed within three to four years of commencement. Although the Company cannot predict with certainty the remaining costs associated with this study, the Company currently estimates that between \$3-4 million of additional spending will be required to complete the study.

Additionally, in April of 2005, the Company completed a Phase III trial examining the potential use of FACTIVE tablets for the five-day treatment of mild to moderate community-acquired pneumonia. Based on the results of this study, in November 2005, the Company submitted a supplemental New Drug Application (sNDA) to the FDA for approval to promote the five-day treatment of FACTIVE tablets for this indication. On September 21, 2006, the Company received an approvable letter from the FDA for the sNDA seeking approval for the five-day treatment CAP with FACTIVE tablets. According to the letter, the Company is required to provide clarification and additional interpretation regarding certain data included in the application to assist the FDA in its evaluation. We recently delivered this additional information to the FDA. The receipt of the approvable letter from the FDA does not assure ultimate approval of the sNDA.

**(d) Accounts Receivable**

Trade accounts receivable consist of amounts due from wholesalers for the purchase of FACTIVE and ANTARA. Ongoing credit evaluations of customers are performed and collateral is generally not required. As of September 30, 2006 and December 31, 2005, the Company has reserved \$34,000 and \$0, respectively, for bad debts related to the sale of FACTIVE and ANTARA. 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 FACTIVE and ANTARA. Amounts past due from customers are determined based on contractual payment terms. Through September 30, 2006, payments have generally been made in a timely manner. The Company also reserved \$310,000 and \$0, respectively, as of September 30, 2006 and December 31, 2006 related to other non-trade receivables.

The following table represents accounts receivable (in thousands):

	As of September 30, 2006	As of December 31, 2005
Trade, net	\$ 7,155	\$ 3,170
Co-promotion	1,745	1,825
Other	318	1,211
Total	\$ 9,218	\$ 6,206

**(e) Restricted Cash**

In connection with the convertible debt offering completed in May 2004, the Company was required to set aside cash in an amount equal to the first six semi-annual interest payments related to such debt. As of September 30, 2006, the Company's restricted cash consists, in part, of the remaining two semi-annual interest payments totaling approximately \$5,346,000 which are payable on October 15, 2006 and April 15, 2007. At September 30, 2006, the restricted cash balance related to the convertible debt offering is approximately \$5,135,000 excluding accrued interest. In addition, 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 and 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. The restrictions related to the South San Francisco facility and the Waltham facility expire on February 28, 2011 and March 31, 2012, respectively.

**(f) Property and Equipment**

The Company records property and equipment at cost. Major replacements and improvements are capitalized, while general repairs and maintenance are expensed as incurred. The Company depreciates its property and equipment over the estimated useful life of the assets using the straight-line method starting when the asset is placed in service. The estimated useful life for leasehold improvements is the term of the lease

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(which is less than the useful life of the assets).

	<b>Estimated Useful Life</b>
Manufacturing and computer equipment	3-5 Years
Equipment and furniture	3-5 Years
Leasehold improvements	7 Years



**Table of Contents**

Depreciation expense was approximately \$564,000 and \$460,000 for the nine-month periods ended September 30, 2006 and 2005, respectively.

**(g) Inventories**

Inventories are stated at the lower of cost or market, with cost determined under the average cost method. Products are removed from inventory and recognized as cost of goods sold on an average cost basis. For FACTIVE, inventories consist of raw material in powder form and work-in-process of approximately \$5,444,000 and \$9,770,000, and FACTIVE finished tablets of approximately \$3,786,000 and \$4,417,000, as of September 30, 2006 and December 31, 2005, respectively. For ANTARA, inventories consist of raw material and work-in-process of approximately \$3,018,000 and \$0, and ANTARA finished capsules of approximately \$2,653,000 and \$0, as of September 30, 2006 and December 31, 2005, respectively.

On a quarterly basis, the Company analyzes its inventory levels, and writes down inventory and marketing samples that have become obsolete, have a cost basis in excess of its 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. At September 30, 2006 and December 31, 2005, there was approximately \$1,142,000 and \$2,072,000, respectively, in FACTIVE sample product to be used for FACTIVE marketing programs and approximately \$498,000 and \$0, respectively, in ANTARA sample product to be used for ANTARA marketing programs. These amounts are classified as other current assets in the accompanying consolidated balance sheet.

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

	As of September 30, 2006	As of December 31, 2005
Raw material	\$ 4,717	\$ 8,418
Work-in-process	3,745	1,352
Finished goods	6,439	4,417
Total	\$ 14,901	\$ 14,187

**(h) Net Loss Per Share (in thousands)**

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 antidilutive. Antidilutive equivalents, which consist of stock options, securities sold under the Company's employee stock purchase plan, directors' deferred stock, convertible notes, warrants and unvested restricted stock that are not included in diluted net loss per share totaled 49,722 and 38,949 shares of the Company's common stock (prior to the application of the treasury stock method) during the three and nine month periods ended September 30, 2006 and 2005, respectively.

**(i) Single Source Suppliers***FACTIVE*

The Company currently obtains the active pharmaceutical ingredient for its commercial requirements for FACTIVE from a single source. 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.



**Table of Contents****(j) Concentration of Credit Risk**

Statement of Financial Accounting Standards (SFAS) No. 105, "Disclosure of Information about Financial Instruments with Off-Balance-Sheet Risk and Financial Instruments with Concentrations of Credit Risk," requires disclosure of any significant off-balance-sheet and credit risk concentrations. The Company has no off-balance-sheet or credit risk concentrations such as foreign exchange contracts, options contracts or other foreign hedging arrangements. The Company maintains its cash and cash equivalents and investment balances with several unaffiliated institutions.

The following table summarizes the number of customers that individually comprise greater than 10% of total revenues and their aggregate percentage of the Company's total product revenues:

	Number of Significant Customers	Percentage of Total Product Revenues by Customer			
		A	B	C	D
Three months ended September 30, 2006	4	28%	31%	11%	19%
Three months ended September 30, 2005	2	70%	*	11%	*
Nine months ended September 30, 2006	3	42%	29%	11%	*
Nine months ended September 30, 2005	2	62%	19%	*	*

\* Balance is less than 10%

The following table summarizes the number of customers that individually comprise greater than 10% of total accounts receivable and their aggregate percentage of the Company's total trade accounts receivable:

	Number of Significant Customers	Percentage of Total Trade Accounts Receivable by Customer			
		A	B	C	D
As of September 30, 2006	4	27%	26%	13%	27%
As of December 31, 2005	2	54%	27%	*	*

\* Balance is less than 10%

To date, the Company has not written off any significant accounts receivable balances.

**(k) 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 condensed financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

**(l) Comprehensive Loss**

The Company follows the provisions of 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. Historically, other comprehensive income had included net loss and change in unrealized gains and losses of marketable securities. For the nine month periods ended September 30, 2006 and 2005, the net loss is equal to the comprehensive loss.

**(m) Reclassifications**

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The Company has reclassified certain prior year information to conform with the current year's presentation. The Company has separately disclosed the operating portion of the cash flows attributable to its discontinued operations, which in prior periods was reported on a combined basis as a single amount.

**Table of Contents****(n) Segment Reporting**

The Company follows the provisions of SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information* (SFAS No. 131). SFAS No. 131 establishes standards for reporting information regarding operating segments in annual financial statements and requires selected information for those segments to be presented in interim financial reports issued to stockholders. SFAS No. 131 also establishes standards for related disclosures about products and services and geographic areas. Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions as to how to allocate resources and assess performance. The Company's chief decision makers, as defined under SFAS No. 131, are the chief executive officer and chief financial officer and have determined that the Company operates in one segment. All of the Company's assets are located in the United States. Approximately 89% of the Company's product revenues are generated from customers based in the United States.

**(o) 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.

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 with its book value, including goodwill. 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 September 30, 2006, the Company does not believe that any of its long-lived assets, goodwill, or intangible assets are impaired.

**(p) Recent Accounting Pronouncements***Accounting for Uncertainty in Income Taxes*

In June 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* an Interpretation of FASB Statement No. 109 (the *Interpretation*). The Interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, *Accounting for Income Taxes*. The Interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. This Interpretation also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Interpretation is effective for fiscal years beginning after December 15, 2006. The Company has not yet completed its evaluation of the Interpretation, but does not currently believe that adoption will have a material impact on its results of operations, financial position or cash flows.

**(3) Acquisition of ANTARA**

On August 18, 2006, the Company acquired the U.S. rights to ANTARA, from Reliant Pharmaceuticals in a transaction being accounted for as an acquisition of a business in accordance with SFAS No. 141, *Business Combinations* and accordingly, allocated the purchase price of ANTARA based upon the estimated fair value of net assets acquired and liabilities assumed. Oscient has performed a preliminary valuation study to determine the allocation of the estimated purchase price of the Antara acquisition among the tangible and intangible assets acquired as well as their estimated amortization period. The preliminary study was performed by a third party and is unaudited. The estimated useful life of the intangible assets is assumed to be fourteen years which was based upon the remaining life of the patents covering ANTARA, the regulatory barriers to competition, and management's knowledge of existing competitors research activities. The Company has completed a preliminary

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analysis of the fair values of the liabilities assumed in connection with the acquisition, including certain liabilities that qualify for recognition under EITF No. 95-3 Recognition of Liabilities in Connection with a Purchase Business Combination (EITF No. 95-3).

**Table of Contents**

The following is a summary of the Company's estimate of the fair values of the assets acquired and liabilities assumed at the date of acquisition (in thousands):

<b>Preliminary estimate of the allocation of purchase price:</b>	
Inventories	\$ 4,344
Prepaid expenses	2,656
Intangible assets	60,900
Goodwill	16,663
Total assets acquired	84,563
Liabilities assumed	(1,427)
Net assets acquired	\$ 83,136
<b>Consideration and direct transaction costs:</b>	
Cash	\$ 82,376
Estimated direct transaction costs	760
Total purchase price	\$ 83,136

The cash consideration consisted of the Company's existing cash funds of \$12,376,000 and \$70,000,000 of funds financed with Paul Royalty Fund Holding II, LP. See further discussion in Note 13.

The following table presents the preliminary estimate of the fair value of the intangible assets acquired, their estimated useful lives and the amortization expense (in thousands):

Intangible assets	Fair value of intangibles	Estimated life (in years)	Amortization for the three and nine months ended September 30, 2006	
			\$	
Developed Technology	\$ 59,020	14	\$	510
Supply Agreement	1,880	14		16
<b>Total</b>	<b>\$ 60,900</b>		<b>\$</b>	<b>526</b>

The following table presents the estimated amortization of the intangible assets acquired (in thousands):

2006	\$ 1,614
2007	4,350
2008	4,350
2009	4,350
2010-2020	46,236
Total	\$ 60,900

The preliminary valuation of the purchased intangible assets of \$60,900,000 was based on the result of a valuation using the income approach and applying a weighted average cost of capital of 17%. On an ongoing basis, Oscient will evaluate the useful life of these intangible assets and

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determine if any competitive, governmental or regulatory event has impaired the value of the assets or modified their estimated useful lives.

### *Supplemental Pro Forma Information*

ANTARA's operations, assumed as of the date of acquisition, are included in the Company's results of operations beginning on August 18, 2006. The unaudited pro forma combined condensed statements of operations for 2006 and 2005 gives effect to the acquisition of ANTARA as if the acquisition of ANTARA had occurred on January 1, 2006 and 2005, respectively.

The unaudited pro forma combined condensed statements of operations are not necessarily indicative of the financial results that would have occurred if the ANTARA acquisition had been consummated on January 1, 2005 nor are they necessarily indicative of the financial results which may be attained in the future.



**Table of Contents**

The pro forma statements of operations are based upon available information and upon certain assumptions that the Company's management believes are reasonable. The ANTARA acquisition is being accounted for using the purchase method of accounting (in thousands, except per share data).

	Nine months ended September 30, 2006			
	2006 (Actual)	(Pro forma)	2005 (Actual)	2005 (Pro forma)
Revenue	\$ 27,888	\$ 32,383	\$ 14,122	\$ 20,008
Total costs and expenses	88,901	96,338	86,828	113,129
Net loss	\$ (63,786)	\$ (71,545)	\$ (71,483)	\$ (95,517)
Weighted average number of shares basic and diluted	91,201	100,522	76,341	87,452
Net loss per share	\$ (0.70)	\$ (0.71)	\$ (0.94)	\$ (1.09)

**(4) Restructuring Plans**

In the fourth quarter of 2004, the Company relocated its corporate headquarters from one facility in Waltham, Massachusetts to a different facility in Waltham, Massachusetts. The Company completed the relocation to obtain administrative space that was needed to support the launch of FACTIVE. The abandonment of the former corporate headquarters was accounted for under SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities. Accordingly, the Company recorded a restructuring charge of approximately \$4.7 million which was comprised of \$2.7 million related to the remaining facility costs that will continue to be incurred through the lease expiration date on November 15, 2006, net of expected sublease payments and \$2.0 million for the write-off of the net book value of the leasehold improvements at the abandoned facility.

The following table summarizes the restructuring activity during the nine month period ended September 30, 2006 (in thousands):

	Balance at December 31, 2005	Cash Payments	Balance at September 30, 2006
Restructuring facility lease liability	\$ 1,076	\$ (904)	\$ 172

At the time of acquisition of 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. In the quarter ended December 31, 2004, in accordance with EITF No. 95-3,

Recognition of Liabilities in Connection with a Purchase Business Combination (EITF No 95-3) the Company made an adjustment to the facilities impairment estimate based on the additional cost of utilities and other related expenses of approximately \$4,730,000. The adjustment was recorded as an additional cost of the acquired company. In the quarter ended December 31, 2005, in accordance with EITF No. 95-3, the Company made an adjustment to the facilities lease liability based on revisions made to estimates of future rental income related to additional subleased space of approximately \$734,000. The adjustment was recorded as a reduction to goodwill.

The following table summarizes the liability activity related to the Genesoft acquisition during the nine month period ended September 30, 2006 (in thousands):

	Balance at December 31, 2005	Cash Payments	Interest Accretion	Balance at September 30, 2006
Assumed facility lease liability	\$ 16,204	\$ (2,166)	\$ 480	\$ 14,518

**(5) Stock-Based Compensation**

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Effective January 1, 2006, the Company adopted SFAS No. 123(R), 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 nine months ended September 30, 2006 includes

**Table of Contents**

(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, 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 its estimate of forfeitures on all unvested awards. Stock-based compensation expense primarily relates to stock options, restricted stock, and stock issued under the Company's employee stock purchase plan. Results for prior periods are not restated.

*Stock Plans*

The Company grants stock options to key employees and consultants under its 1991, 1993, 1995 and 1997 Stock Option Plans, as well as the 2001 Incentive Plan (collectively, the Option Plans). The Stock Option and Compensation Committee of the Board of Directors determines the purchase price and vesting schedule applicable to each option grant. As of September 30, 2006, there are no shares reserved for future grants under the 1991, 1993, 1995 and 1997 Plans. The 2001 Incentive Plan provides for the grant of non-qualified stock options, incentive stock options, restricted stock, stock appreciation rights, unrestricted stock, deferred stock, and cash performance awards. Generally, options granted to employees vest based on service conditions over a two to four year time period and options granted to non-employees vest based on service conditions over a one to three year time period, all of which have graded vesting. All options granted to both employees and non-employees have a contractual term of ten years from date of grant and generally, the exercise price of the stock options equals the fair market value of the Company's common stock on the date of grant. Certain option awards provide for accelerated vesting if there is a change in control. As of September 30, 2006, 14,400,000 shares were authorized and 5,867,863 shares were available under the 2001 Incentive Plan for future issuance. 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 524,046 options to purchase common stock.

*Employee Stock Purchase Plan*

The Company also has an Employee Stock Purchase Plan (ESPP), which was adopted in February 2000. Under the ESPP, eligible employees may contribute up to 15% of their earnings toward the semi-annual purchase of the Company's common stock. The employees' purchase price is 85% of the fair market value of the common stock at the time of grant of option or the time at which the option is deemed exercised, whichever is less. The most recently completed offering period began January 1, 2006 and ended on June 30, 2006; therefore, January 1, 2006 is considered the grant date for the purposes of recognizing the stock-based compensation expense for this offering period. The Company projects the estimated contributions at the beginning of the period and uses the Black-Scholes-Merton option-pricing model in order to determine the estimated fair value of the stock to be issued. At the end of the offering period, the Company adjusts the estimated contributions to actual. Under Accounting Principles Board Opinion (APB) No. 25, Accounting for Stock Issued to Employees (APB No. 25), the Company was not required to recognize stock-based compensation expense for the cost of stock options or shares issued under the Company's ESPP because the ESPP was determined to be noncompensatory. Upon adoption of SFAS 123R, the Company began recording stock-based compensation expense related to the ESPP. As of September 30, 2006, 2,250,000 shares were authorized and 765,546 shares were available for future issuance under this plan.

Prior to January 1, 2006, the Company applied the intrinsic value method under APB Opinion No. 25 Accounting for Stock Issued to Employees (APB No. 25) and related interpretations, in accounting for its stock-based compensation plans for awards to employees, rather than the alternative fair value accounting method provided for under SFAS No. 123. Under APB No. 25, when the exercise price of options granted under these plans equals the market price of the underlying stock on the date of grant, no compensation expense is required. In accordance with EITF No. 96-18, Accounting for Equity Instruments That are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services (EITF No. 96-18), the Company records compensation expense equal to the fair value of options granted to non-employees over the period of service, which is generally the vesting period. The Company generally used the straight-line method of amortization for stock-based compensation. Had compensation cost for these plans been determined consistent with SFAS No. 123R, the Company's consolidated net loss and net loss per share would have been increased to the following pro forma amounts (in thousands, except per share amounts):

	<b>Three Months Ended September 30, 2005</b>	<b>Nine Months Ended September 30, 2005</b>
Net loss as reported	\$ (21,903)	\$ (71,483)
Add: Share-based employee compensation cost, included in the determination of net loss as reported	6	1,000
Less: Total share-based compensation expense determined under the fair value method for all employee awards	(1,056)	(6,528)

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Pro forma net loss	\$ (22,953)	\$ (77,011)
<b>Basic and diluted net loss per share</b>		
As reported	\$ (0.29)	\$ (0.94)
Pro forma	\$ (0.30)	\$ (1.01)

**Table of Contents**

The adoption of SFAS No. 123R increased the Company's three and nine months ended September 30, 2006 operating loss, net loss, and cash flows used in operating activities by \$1,020,000 and \$3,063,000, respectively and basic and diluted net loss per share by \$0.01 and \$0.03, 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. Additionally, the Company eliminated the January 1, 2006 deferred compensation balance against additional paid-in capital upon adoption of SFAS No. 123R.

The fair value of each option award is estimated on the grant date using the Black-Scholes-Merton option-pricing model based on the assumptions noted in the following table:

	Three Months Ended September 30,		Three Months Ended September 30,		Nine Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2005	2005	2006	2005	2005	2005
Expected volatility	56.20	61.62%	52.29	52.75%	52.14	61.62%	48.35	52.75%
Risk-free interest rate	4.68	5.05%	3.98	4.12%	4.35	5.07%	3.71	4.17%
Expected life (years)	5.55	6.17		5	5.00	6.25		5
Expected dividend								

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 is applied to one group as a whole as the Company does not expect substantially different exercise or post-vesting termination behavior amongst its employee population. The Company will continue to review the expected life among the employee population to determine whether multiple groups is necessary.

Volatility is determined exclusively based on historical volatility data of the Company's common stock from the period of time beginning with the Company's merger with Genesoft in February 2004 through the month of grant. 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. The Company has not paid and does not anticipate paying cash dividends, therefore the expected dividend yield is assumed to be 0%.

A summary of activity related to stock options under the Option Plans as of September 30, 2006, and changes during the nine month period then ended is presented below (in thousands, except weighted average data):

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2005	8,861	\$ 4.06		
Granted	1,818	\$ 1.74		
Exercised	(715)	\$ 0.17		
Forfeited/Cancelled	(1,893)	\$ 3.86		
Outstanding at September 30, 2006	8,071	\$ 3.93	7.79	\$ 118
Exercisable at September 30, 2006	4,409	\$ 5.00	6.97	\$ 105

The total compensation cost that has been charged to income during the third quarter of 2006 was approximately \$1,020,000. The Company's policy is to recognize compensation cost for awards with service conditions and graded vesting using the straight-line method. Additionally the Company's 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 123R requires forfeitures to be

**Table of Contents**

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. The Company estimates forfeitures based on historical data, adjusted for known trends, calculated with the assistance of the independent third party. The Company has applied an annual forfeiture rate of 23.24% to options in calculating total recognized compensation cost as of September 30, 2006. This analysis will be re-evaluated quarterly 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.

Using the Black-Scholes-Merton option-pricing model, the weighted average grant date fair values of options granted during the nine months ended September 30, 2006 and 2005 were \$0.94 and \$1.21, respectively. For the nine months ended September 30, 2006, the Company granted 1,818,000 in stock options with a weighted average exercise price of \$1.74. For the nine months ended September 30, 2005, the Company granted 4,030,676 in stock options with a weighted average exercise price of \$2.52.

During the nine months ended September 30, 2006 and 2005, the total intrinsic value of options exercised was \$616,000 and \$2,218,000, respectively. The total amount of cash received from exercise of these options during the nine months ended September 30, 2006 and 2005 was \$169,000 and \$546,000 respectively.

The 2001 Incentive Plan also provides for awards of nontransferable shares of restricted common stock which are subject to forfeiture. All shares of restricted stock vest based on service conditions in two equal installments over a two-year period. Generally, the fair value of each restricted stock award is equal to the market price of the Company's stock at the date of grant. Certain restricted share awards provide for accelerated vesting if there is a change in control.

A summary of activity related to restricted stock under the Option Plans as of September 30, 2006, is indicated in the following table (in thousands, except weighted average data):

	Number of Shares	Weighted-Average Grant Date Fair Value
Nonvested at December 31, 2005		\$
Granted	614	\$ 1.71
Vested		
Forfeited	(38)	\$ 1.91
Nonvested at September 30, 2006	576	\$ 1.70

As of September 30, 2006, there was \$6,230,000 of total unrecognized compensation cost related to unvested share based awards. This cost is expected to be recognized over a weighted average remaining requisite service period of 1.7 years. The Company expects approximately 2,812,000 in unvested options to vest at some point in the future. Options expected to vest are calculated by applying an estimated forfeiture rate to the unvested options.

**(6) Cash, Cash Equivalents and Marketable Securities**

The Company applies the provisions of SFAS No. 115, Accounting for Certain Investments in Debt and Equity Securities. At December 31, 2005, the Company's investments included short-term marketable securities. Cash equivalents are short-term, highly liquid investments with maturities of 90 days or less. Marketable securities are investment securities with original maturities of greater than 90 days. Cash equivalents are carried at cost, which approximates fair value. Marketable securities that are classified as held-to-maturity are recorded at amortized cost, which approximates fair value. At September 30, 2006 and December 31, 2005, cash and cash equivalents consisted of money market funds and commercial paper, and marketable securities consisted of short-term corporate obligations. At September 30, 2006 and December 31, 2005, the average maturity of the Company's investments was approximately 1 month and 0.9 months, respectively. At December 31, 2005, the Company had a net unrealized loss of approximately \$1,000, which is the difference between the amortized cost and the fair value of the held-to-maturity investments related to government and well capitalized corporations. Therefore, the Company deemed the loss to be temporary. The fair value of the Company's cash equivalents and marketable securities is determined based on market value.

**Table of Contents**

At September 30, 2006 and December 31, 2005, the Company's cash, cash equivalents and marketable securities consisted of the following (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
<b>September 30, 2006</b>				
Cash and Cash Equivalents:				
Cash	\$ 39,835	\$	\$	\$ 39,835
Money market funds	2,636			2,636
Commercial paper	299			299
Total cash and cash equivalents	\$ 42,770	\$	\$	\$ 42,770
<b>December 31, 2005</b>				
Cash and Cash Equivalents:				
Cash	\$ 43,069	\$	\$	\$ 43,069
Money market funds	11,326			11,326
Commercial paper	11,223	4		11,227
Total cash and cash equivalents	\$ 65,618	\$ 4	\$	\$ 65,622
Marketable Securities (held-to-maturity):				
Short-term corporate obligations	\$ 2,696	\$	\$ (1)	\$ 2,695
Total short-term marketable securities	\$ 2,696	\$	\$ (1)	\$ 2,695

**(7) Notes Receivable**

In connection with a lease agreement associated with vehicles for the Company's sales representatives, the Company was issued notes by the lessor totaling approximately \$2,926,000 related to the repayment of security deposits made by the Company. The notes bear interest at rates ranging from 5.5% to 7.75% and have expiration dates ranging from March 2008 to December 2008. Principal and interest are repaid by the lessor to the Company over the 36 month lease term as lease payments are made on the vehicles.

**(8) Long-Term Obligations**

In the quarter ended June 30, 2004, the Company issued \$152,750,000 in principal amount of its 3.5% senior convertible promissory notes due in April 2011. These notes are convertible into the Company's common stock at the option of the holders at a conversion price of approximately \$6.64 per share. The Company may not elect to redeem the notes before May 10, 2010. After this date, the Company can redeem all or a part of the notes for cash at a price equal to 100% of the principal amount of the notes to be redeemed plus accrued and unpaid interest. Upon the occurrence of a termination of trading of the Company's common stock or a change of control transaction in which substantially all of the Company's common stock is exchanged for consideration other than common stock that is listed on a U.S. national securities exchange or market (such as NASDAQ), holders of these 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. In addition, in the case of a change of control transaction in which all of the consideration paid for the Company's common stock consists of cash, the Company may have an obligation to pay an additional make-whole premium to the note holders based on a formula set forth in the indenture. In connection with the issuance, the Company recorded deferred financing costs of \$5,708,000 which is being amortized to interest expense on a straight-line basis over the period the notes are outstanding. A portion of the net proceeds from the offering was used to purchase U.S. government securities as pledged collateral to secure the first six scheduled interest payments on the notes, the unpaid portions of which are classified as restricted cash on the September 30, 2006 and December 31, 2005 consolidated balance sheets. As part of the issuance, the Company filed a shelf registration statement relating to the resale of the notes and the common stock issuable upon conversion.

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On February 6, 2004, in connection with the merger with Genesoft, the Company issued \$22,309,647 in principal amount of 5% convertible promissory notes due in February 2009. These notes are convertible into the Company's common stock at the option of the holders, at a conversion price of approximately \$6.64 per share (subject to anti-dilution and other adjustments). In addition, the Company has the right to force conversion if the price of its common stock closes above 150% of the then effective conversion price for 15 consecutive trading days. At the closing of the merger, the holders of these notes also received an aggregate 4,813,547 shares of the Company's common stock representing the payment of accrued interest and related amounts on certain outstanding notes previously issued to such holders by Genesoft.

In connection with the acquisition of ANTARA in August 2006, the Company, together with its wholly-owned subsidiary Guardian II Acquisition Corporation (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 ( PRF ), including a \$40 million revenue interest assignment arrangement, the issuance of a Note in the amount of \$20 million and the issuance of Common Stock and Warrants in consideration for \$10 million. See further discussion in Note 13.



## **Table of Contents**

### **(9) Supply Agreement for FACTIVE**

In October 2002, Genesoft, now a subsidiary of the Company, entered into a license and option agreement with LG Life Sciences to develop and commercialize 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 and Vatican City. This agreement subsequently was assigned to the Company. 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 currently issued patents for composition of matter expires in 2018. The term could extend further depending upon several factors, including the timing of the commercial sale of the product in a particular country. The product was approved for sale in the United States in April 2003 for the treatment of acute bacterial exacerbation of chronic bronchitis and community-acquired pneumonia of mild to moderate severity.

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 the Company's anticipated commercial requirements for FACTIVE bulk drug substance. LG Life Sciences currently supplies the FACTIVE bulk drug substance from its manufacturing facility in South Korea.

The agreement also requires the Company to achieve a minimum level of FACTIVE sales over a period of time, which if not met, would result in the technology being 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 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 gemifloxacin in the Company's territory; provided, that LG Life Sciences has the right to co-promote the product, on terms to be negotiated, in the Company's territory for 2008 and periods commencing thereafter, in which case the Company's royalty obligations to LG Life Sciences would cease. In an amendment dated March 31, 2005 as further described below, LG Life Sciences' right to co-promote will terminate upon the Company reaching a certain level of sales.

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 the expiration of the patents covering FACTIVE in such country or ten years following the first commercial sale of FACTIVE in such country. Pursuant to the license and option agreement, as amended to date, the Company is also obligated to make aggregate milestone payments of up to \$31 million (not including upfront payments) to LG Life Sciences upon achievement of additional regulatory approvals and sales thresholds and upon consummation of sublicensing agreements.

On March 31, 2005, the Company amended its license and option agreement with LG Life Sciences. As part of the amendment of the agreement, the Company made a one time, upfront, payment of \$2 million to LG Life Sciences which was recorded to general and administrative expense in the three month period ended March 31, 2005 and agreed to make certain additional milestone payments upon obtaining regulatory approvals and sales thresholds. The amended agreement also includes a reduction of future royalties payable to LG Life Sciences at certain FACTIVE revenue levels in territories covered by the agreement.

The Company further amended its 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 if the Company consummates sublicense agreements in such countries prior to dates specified in the amendment. As part of the amendment to the agreement, the Company made a one-time, up front non-refundable payment to LG Life Sciences which was deferred and is being recorded to general and administrative expense over the expected term of the respective sublicensing agreement. The modified agreement also calls for additional milestone payments to LG Life Sciences upon consummation of sublicense agreements in Mexico and Canada as well as upon receipt of regulatory approval of FACTIVE in each of such countries.

**Table of Contents****(10) Supply Agreement for ANTARA**

In accordance with the acquisition of ANTARA in August of 2006, the Company was assigned rights to and assumed 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 and Canada until February 2012 or pay amounts to Ethypharm to compensate for any shortfall. During the term of the agreement with Ethypharm, the Company is obligated to pay a royalty on sales of ANTARA in the U.S, including a royalty on other fenofibrate monotherapy products in formulation 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 bulk product 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 using commercially reasonable efforts to maintain a sales force of at least 150 representatives through February 2008 and funding a portion of the active pharmaceutical ingredient safety stock that Ethypharm is required to maintain.

**(11) Co-Promotion of TESTIM**

On April 11, 2005, the Company entered into a co-promotion agreement with Auxilium Pharmaceuticals, Inc. (Auxilium), under which the Company and Auxilium co-promoted in the United States Auxilium's product, TESTIM gel, a topical 1% testosterone gel indicated for the treatment of male hypogonadism. On August 31, 2006, the Company and Auxilium mutually agreed to conclude this co-promotion arrangement and agreed to share profits from primary care sales, as provided for under the Co-Promotion Agreement, through August 31, 2006. As part of the termination of the Co-Promotion agreement, the Company received \$1,800,000 from Auxilium as additional compensation for commercialization efforts by its sales force through August 31, 2006, which has been recognized as revenue during the three and nine months ended September 30, 2006.

**(12) Partnering Arrangements for FACTIVE***Sublicense Agreement with Pfizer, S.A. de C.V.*

On February 6, 2006, the Company entered into a Sublicensing and Distribution Agreement with Pfizer, S.A. de C.V. (Pfizer Mexico), pursuant to which the Company sublicensed its rights to sell FACTIVE tablets in Mexico to Pfizer Mexico. In exchange for those rights, Pfizer Mexico has agreed to pay the Company an up-front payment, milestone payments upon obtaining certain regulatory approvals and sales goals as well as royalties on future sales. The upfront payment is being recognized as revenue over the term of the Company's 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 the Company, and the Company must exclusively supply, all active pharmaceutical ingredients 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 six months prior written notice. Upon termination of the Pfizer Agreement, Pfizer Mexico is obligated to assign any and all rights to regulatory approvals in Mexico to the Company or its designee.

*Supply and Marketing Agreement with Abbott Laboratories*

On August 9, 2006, the Company granted the commercialization rights to FACTIVE tablets in Canada to Abbott Canada, the Canadian affiliate of Abbott Laboratories. In exchange for those rights, Abbott Canada agreed to a transfer price on product purchases and to make certain payments to the Company upon achievement of certain regulatory and sales milestones. FACTIVE tablets are currently approved in Canada for the five-day treatment of AECB.

**(13) 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), entered into several financing agreements with Paul Royalty Fund Holdings II, LP, an affiliate of Paul Capital Partners (PRF), including a Revenue Interest Assignment Agreement, and a Note Purchase Agreement, presented under long term debt, and a Common Stock and Warrant Purchase Agreement, presented in equity, in consideration for an aggregate amount of \$70 million.



**Table of Contents***Revenue Interests Assignment Agreement*

The Company and Guardian II entered into a Revenue Interest Assignment Agreement (the *Revenue Agreement*), pursuant to which it sold to PRF the right to receive specified royalties on Guardian II's and Oscient's net sales in the United States (and the net sales of their respective affiliates and licensees) of the ANTARA capsules and FACTIVE tablets, respectively until December 31, 2016. The royalty payable to PRF 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 PRF exceed \$100 million, the royalties become nominal.

In connection with the transaction, the Company recorded a liability, referred to as the revenue interest liability, of approximately \$40 million in accordance with EITF 88-18, *Sales of Future Revenues*. The Company will impute interest expense associated with this liability using the effective interest rate method and will record 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 PRF as a result of ANTARA and FACTIVE sales levels will reduce the accrued interest liability and the principal amount of the revenue interest liability. Through September 30, 2006, there have been no payments made to PRF 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*), PRF has the right to require us to repurchase from PRF its royalty interest at a price in cash which equals the greater of (a) a specified multiple of cumulative payments made by PRF under the Revenue Agreement less the cumulative royalties previously to PRF; or (b) the amount which will provide PRF, when taken together with the royalties previously paid, a specified rate of return (the *Put/Call Price*). Upon a bankruptcy event, the Company is automatically required to repurchase the PRF 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 PRF royalty interest for an amount equal to the Put/Call Price. The Company has determined that PRF'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 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, *Accounting for Derivatives Instruments and Hedging Activities*. This liability will be 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 September 30, 2006, no gain or loss has been recorded.

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 has the right, but not the obligation, to reduce the royalty percentages due under the Revenue Agreement to PRF by fifty percent (50%) by paying PRF a price in cash which will provide PRF, 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 has the right, but not the obligation, to repurchase the PRF royalty interest at a price in cash which will provide PRF, 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 PRF 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 PRF, 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 \$0.8680, with an exercise price of \$.8680 per share. If the Company exercises such option, the number of shares subject to the warrant issuable to PRF would be between 2,304,147 shares and 2,940,230 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 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 shall become immediately due and payable.



**Table of Contents**

Subject to the Revenue Agreement and the Note Purchase Agreement, without the prior written consent of PRF, 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 products and FACTIVE, (ii) enter into any new agreement or amend or fail to exercise any of its material rights under existing agreements that would adversely affect PRF'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 PRF entered into a Security Agreement (the Security Agreement ) under which Guardian II granted to PRF 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 PRF 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 PRF 11,111,111 shares (the Shares ) of the Common Stock, at a price of \$0.90 per share (the Private Placement ) and issued PRF a warrant (the Warrant ) to purchase 2,304,147 shares of Common Stock (the Warrant Shares ) at an exercise price of \$0.8680 per share. The Warrant is exercisable for seven years from the date of closing. The Warrant contains a cashless exercise option and penalties if the Company does not deliver the applicable amount of Warrant Shares within three trading days of exercise of a Warrant by PRF. The Warrant also contains provisions providing that, at PRF's election, the Company must re-purchase the Warrant from PRF upon a sale of the Company in which the consideration for such sale is solely cash.

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## **Table of Contents**

### **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 FACTIVE® and ANTARA®, our discount and rebate programs for FACTIVE and ANTARA, expected commercialization of ANTARA by our sales force and the continued growth of the brand, our ability to obtain approval from the U.S. Food and Drug Administration (FDA) for a five-day course of therapy for CAP, our ability to secure a long term source of bulk drug supply for Ramoplanin 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 are intended to 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 the statements.

#### **Overview**

We are a commercial-stage biopharmaceutical company marketing two FDA-approved products with our national primary care sales force a fluoroquinolone antibiotic, FACTIVE® (gemifloxacin mesylate) tablets, and a cardiovascular product, ANTARA® 130 mg and ANTARA® 43 mg (fenofibrate) capsules. FACTIVE is indicated for the treatment of community-acquired pneumonia of mild to moderate severity (CAP) and acute bacterial exacerbations of chronic bronchitis (AECB). We license the rights to gemifloxacin, the active ingredient in FACTIVE tablets, from LG Life Sciences of the Republic of Korea. FACTIVE was launched in the U.S. market in September 2004. ANTARA is approved by the U.S. Food and Drug Administration to treat hypercholesterolemia (high blood cholesterol) and hypertriglyceridemia (high triglycerides) in combination with a healthy diet. ANTARA is part of the \$22 billion U.S. market for treating dyslipidemias, which includes the \$1 billion fenofibrate market, and Oscient's national sales force began marketing ANTARA in late August 2006. We license the U.S. rights to ANTARA from Ethypharm S.A. Additionally, we have a novel, late-stage antibiotic candidate, Ramoplanin, under investigation for the treatment of *Clostridium difficile*-associated disease and have begun exploring partnering and other strategic opportunities for the continued development of Ramoplanin.

We have incurred significant operating losses since our inception. As of September 30, 2006, we had an accumulated deficit of approximately \$401 million. We expect to incur additional operating losses over the next several years due to the implementation of manufacturing, distribution, marketing and sales capabilities.

#### **FACTIVE**

##### *Overview*

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. The product was approved for sale in the United States in April 2003 for such indications.

In October 2002, we entered into a license and option agreement with LG Life Sciences to develop and commercialize gemifloxacin, 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 and Vatican City. 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 currently issued patents for composition of matter expires in 2018.

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 bulk drug substance. LG Life Sciences currently supplies the FACTIVE bulk drug substance from its manufacturing facility in South Korea.





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## **Table of Contents**

The agreement with LG Life Sciences also requires a minimum sales commitment over a period of time, which if not met, would result in the technology being 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 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 gemifloxacin in our territory; provided, that LG Life Sciences has the right to co-promote the product, on terms to be negotiated, in our territory commencing in 2008 and for periods thereafter, in which case our royalty obligations to LG Life Sciences would cease. Pursuant to an amendment dated March 31, 2005 as further described below, LG Life Sciences' right to co-promote in the U.S. will terminate upon our reaching a certain level of sales.

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 the expiration of the patents covering FACTIVE in such country or ten years following the first commercial sale of FACTIVE in such country. Pursuant to the license and option agreement, as amended to date, we are also obligated to make aggregate milestone payments of up to \$31 million (not including upfront payments) to LG Life Sciences upon achievement of additional regulatory approvals and sales thresholds and upon consummation of sublicensing agreements.

On March 31, 2005, we amended our license and option agreement with LG Life Sciences. As part of the amendment of the agreement, we made a one time, upfront payment of \$2 million to LG Life Sciences which was recorded to general and administrative expense in the three month period ended March 31, 2005 and agreed to make certain milestone payments upon obtaining regulatory approvals and sales thresholds. The amended agreement also includes 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 if we consummate sublicense agreements in such countries prior to dates specified in the amendment. The modified agreement also calls for milestone payments to be made to LG Life Sciences upon consummation of sublicense agreements in Mexico and Canada as well as upon receipt of regulatory approval of FACTIVE in each of such countries.

### *Commercialization and Development*

We began selling FACTIVE tablets in September 2004 with an initial sales force of 100 representatives and, as of September 2006, utilize a full-time sales force of approximately 250 sales representatives, which are supplemented by approximately 30 part-time sales personnel who began work in June 2006.

With respect to the additional development initiatives, we have completed a clinical trial to demonstrate that a five-day course of FACTIVE for the treatment of mild to moderate CAP is as effective as the currently 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. According to the letter, we were required to provide clarification and additional interpretation regarding certain data included in the application to assist the FDA in its evaluation. We recently delivered this additional information to the FDA and are waiting a reply from the FDA regarding the completeness of the response. The receipt of the approvable letter from the FDA does not assure ultimate approval of the sNDA.

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. On September 12, 2006, the FDA's Anti-Infective Drugs Advisory Committee voted not to recommend approval of this sNDA. We have since withdrawn 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 those rights, Pfizer Mexico has agreed to pay us an up-front license fee, milestone payments upon obtaining certain regulatory approvals and sales goals as well as royalties on future sales. In accordance with EITF No. 00-21, the up-front license payment related to the Pfizer Mexico license agreement will be recognized as revenue over eighteen months. 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 active pharmaceutical ingredients 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 six months prior written notice. Upon termination of the Pfizer Agreement, Pfizer Mexico is obligated to assign any and all rights to regulatory



## **Table of Contents**

approvals in Mexico to us or our designee. On August 1, 2006, we announced that we 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. Accordingly, in October 2006, Pfizer Mexico launched the promotion of FACTIVE in Mexico utilizing three national sales forces and one specialty sales force.

On August 9, 2006, we granted the commercialization rights to FACTIVE tablets in Canada to 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, and Abbott Canada plans to launch FACTIVE for the treatment of AECB in the coming months.

## **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 low-density lipoprotein cholesterol (LDL or bad cholesterol), triglyceride and Apolipoprotein B (free floating fats in the blood) levels, and to increase high-density lipoprotein cholesterol (HDL or good cholesterol) in adult patients with high cholesterol or an abnormal concentration of lipids in the blood. Fenofibrates work primarily to lower triglycerides and increase HDL cholesterol, which makes the drug an attractive alternative for those patients whose LDL cholesterol is well controlled. ANTARA is approved and marketed in 43 mg and 130 mg doses. ANTARA received FDA approval in November 2004.

On August 18, 2006, we acquired rights to ANTARA in the United States from Reliant Pharmaceuticals Inc. for \$78 million plus an approximately \$4.3 million payment for ANTARA inventory, exclusive of estimated transaction costs. In accordance with our acquisition of ANTARA, we were assigned rights to and assumed obligations under an exclusive license to the rights to ANTARA from Ethypharm S.A. In order to maintain the exclusivity of our rights, we 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 with Ethypharm, we are obligated to pay a royalty on sales of ANTARA in the U.S., including a royalty on other fenofibrate monotherapy products in formulation and dosage forms that may be substantially similar or identical to ANTARA developed by us. In addition, during the third quarter of 2006, a sales-based milestone was met which will result in the Company paying \$400,000 to Ethypharm in the fourth quarter. This milestone payment was recorded as a liability in purchase accounting. 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 our option, Ethypharm is obligated to either manufacture and deliver to us finished fenofibrate product or deliver bulk product to us for encapsulation and packaging. Ethypharm also has a right of first refusal on any divestiture of the ANTARA rights by Oscient. Additional Oscient obligations under the Ethypharm agreement include using commercially reasonable efforts to maintain a sales force of at least 150 representatives through February 2008 and 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 NDA and the IND covering the ANTARA products in the United States, clinical data, inventory, the ANTARA® 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 related 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 which we develop, which include all products containing fenofibrate as its active pharmaceutical ingredient. 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.

ANTARA capsules are protected by patents relating to formulations containing fenofibrate and methods of preparing the same that expire in August 2007 and 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.

## **Co-Promotion of TESTIM**

On April 11, 2005, we entered into a co-promotion agreement with Auxilium Pharmaceuticals, Inc. under which we and Auxilium co-promoted in the United States Auxilium's product, TESTIM gel, a topical 1% testosterone gel indicated for the treatment of male hypogonadism. On August 31, 2006, we mutually agreed with Auxilium to terminate this co-promotion arrangement and agreed with Auxilium to



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## **Table of Contents**

share profits from primary care sales, as provided for under the Co-Promotion Agreement, through August 31, 2006. As part of the termination of the Co-Promotion agreement, we received \$1,800,000 from Auxilium as additional compensation for commercialization efforts by its sales force through August 31, 2006. which has been recognized as revenue in the quarter ended September 30, 2006.

### **Research and Development Programs**

#### **FACTIVE**

As a condition to the approval to sell FACTIVE tablets, the FDA has required, as a post-marketing study commitment, that we conduct a prospective, randomized study comparing FACTIVE tablets (5,000 patients) to 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 includes patients of different ethnicities to gain safety information in populations not substantially represented in the existing clinical trial program. Patient enrollment for this Phase IV trial, with approval from the FDA, commenced patient enrollment during the fall of 2004 and is scheduled to be completed within three to four years from commencement of the trial. Although we cannot predict with certainty the costs necessary to complete this study, we currently estimate it will cost between \$3-4 million of additional spending to complete the study.

Additionally, in April of 2005, we completed a Phase III trial examining the potential use of FACTIVE tablets for the five-day treatment of mild to moderate community-acquired pneumonia. Based on the results of this study, in November 2005 we submitted a supplemental New Drug Application 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. According to the terms of letter, we were required to provide clarification and additional interpretation regarding certain data included in the application to assist the FDA in its evaluation. We recently delivered this additional information to the FDA and are awaiting a reply from the FDA regarding the completeness of the response. Receipt of the approvable letter from the FDA does not assure approval of the sNDA.

#### **Ramoplanin**

We are developing 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. During the second quarter of 2006, we initiated production of clinical trial materials and began site identification and site qualification activities for the Phase III program. With the agreement to acquire ANTARA and heightened interest in new alternatives for treating *Clostridium-difficile* associated disease, we have been exploring partnering and other strategic opportunities for Ramoplanin, in part to reduce the financial impact of the Phase III program. Although we are in a position to begin the Phase III program, we have decided not to commence significant investment in this program while these partnering discussions are underway.

### **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 of this Quarterly Report on Form 10-Q. Our preparation of this Report 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:

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

Our principal source of revenue is the sale of FACTIVE tablets and ANTARA capsules. In the second quarter of 2005, we began recognizing co-promotion revenue in connection with our co-promotion agreement with Auxilium Pharmaceuticals, Inc. (Auxilium), which terminated on August 31, 2006. Other historical sources of revenue include biopharmaceutical alliances and royalties from the divested genomic services business. In future periods, we expect our revenues derived from biopharmaceutical alliances will continue to decrease, however product revenues will continue to increase based on anticipated increased volume of prescriptions of FACTIVE tablets and ANTARA capsules.



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## **Table of Contents**

Although ANTARA revenue results are anticipated to be steady through our fiscal year, we expect demand for FACTIVE to be highest from November 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, 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 No. 104, Revenue Recognition (a replacement of SAB 101) (SAB 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. Also, the cost of FACTIVE and ANTARA associated with amounts recorded as deferred revenue is recorded in inventory until such time as risk of loss has passed.

### *Co-Promotion Revenue*

Amounts earned under our co-promotion agreement with Auxilium from the sale of TESTIM gel, a product developed by Auxilium, are classified as co-promotion revenue in our consolidated statements of operations. Auxilium is obligated to pay us a co-promotion fee based on a specified percentage of the gross profit from TESTIM sales attributable to primary care physicians in the U.S. that exceeds a specified cumulative sales threshold, determined on an annual basis. The specific percentage is based upon TESTIM sales levels attributable to primary care physicians and the marketing expenses incurred by us in connection with the promotion of TESTIM under the co-promotion agreement. Such co-promotion revenue is earned when TESTIM units are dispensed through patient prescriptions. The arrangement contains a clause that provides Auxilium the ability to recover revenue if specified cumulative sales thresholds are not met. There is no cost of goods sold associated with co-promotion revenue, and the selling and marketing expenses incurred with respect to the co-promotion arrangement are classified as selling and marketing expenses in our consolidated statements of operations. On August 31, 2006, we mutually agreed with Auxilium to conclude this co-promotion arrangement and agreed with Auxilium to share profits from primary care sales, as provided for under the Co-Promotion Agreement, through August 31, 2006. As part of the termination of the Co-Promotion agreement, we received \$1,800,000 from Auxilium as additional compensation for commercialization efforts by our sales force through August 31, 2006, which has been recognized as revenue in the quarter ended September 30, 2006.

### *Biopharmaceutical/Other Revenue*

Prior to our merger with GeneSoft Pharmaceuticals, Inc. in 2004, we pursued biopharmaceutical revenues through alliance partnerships with pharmaceutical companies and through government grants. Biopharmaceutical revenues have consisted of government research grants and license fees, contract research, and milestone payments from alliances with pharmaceutical companies. Genomics services revenues have consisted of government sequencing grants, fees and royalties received from custom gene sequencing, and analysis services. We have now shifted our focus to the development and commercialization of pharmaceutical products. The declining revenues and associated expenses for the genomics services business have been classified as discontinued operations in the consolidated financial statements.

Other revenues consist of sublicensing revenues related to FACTIVE. We recognize revenue in accordance with SAB No. 104 and Emerging Issues Task Force Issue No. (EITF) 00-21, Revenue Arrangements with Multiple Deliverables (EITF No. 00-21). In accordance with EITF No. 00-21, the up-front license payment related to the Pfizer Mexico license agreement will be recognized as revenue over the term of the Company's continuing obligations, which is eighteen months. In addition, on August 1, 2006, we announced that we 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 during the three and nine months ended September 30, 2006.

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

Our FACTIVE and ANTARA product sales are made 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





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## **Table of Contents**

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 our estimate of future FACTIVE and ANTARA 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, return rates for similar competitive antibiotic products that have a similar shelf life and are sold in the same distribution channel, 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 six months subsequent to the expiration date of our product. FACTIVE tablets and ANTARA capsules each have a 36-month expiration period from the date of manufacturing. At September 30, 2006 and December 31, 2005, our product return reserve was approximately \$573,000 and \$720,000, 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 sheet. As of September 30, 2006 and December 31, 2005, the balance for cash discounts reserve was approximately \$111,000 and \$50,000, respectively.

### *Rebates*

The liability for managed care rebates is calculated based on historical and current rebate redemption and utilization rates contractually submitted by each state. As of September 30, 2006 and December 31, 2005 the balance of the accrual for managed care and Medicaid rebates for ANTARA and FACTIVE was approximately \$975,000 and \$381,000, respectively. Considering the estimates made by us, as well as estimates prepared by third party utilization reports that are necessary in evaluating the required liability balance, we believe our estimates are reasonable. As of September 30, 2006, the significant change to our estimates in the periods presented is primarily attributable to the acquisition of the ANTARA product line.

### *Special Promotional Programs:*

We have from time to time, offered certain promotional incentives to our customers for both FACTIVE and ANTARA and may continue this practice in the future. Such programs include: sample cards to end consumers, certain product rebates to pharmacy customers, and other sales stocking allowances. Examples of programs utilized to date follow:

#### *Sample Card Program for FACTIVE*

During the second quarter of 2006, we initiated two sample card programs whereby we offered an incentive to patients in the form of a free full-course sample card for FACTIVE. We have accounted for these programs in accordance with EITF No. 01-09, Accounting for Consideration Given by a Vendor to a Customer (EITF No. 01-09). For the first sample card program, we were able to develop a reasonable and reliable estimate of the amount of expected reimbursement claims based on actual claims submitted by and processed by a third party claims processing organization. For the second sample card program, the estimate of expected reimbursement claims was based on the historical actual reimbursement claims for the similar completed programs that we conducted in the first and second quarters of 2006. The first program expired on June 15, 2006 and the second program expired on September 30, 2006. The balance of the liability as of September 30, 2006 for these sample card programs was approximately \$256,000.

#### *Voucher Rebate Program for FACTIVE*

During the second and third quarters of 2006, we initiated three voucher rebate programs whereby we offered mail-in rebates to retail consumers. We have accounted for these programs in accordance with EITF No. 01-09. The liabilities we recorded for these voucher rebate programs were estimated based upon the historical rebate redemption rates for the similar completed programs that commenced in the first quarter of 2005, fourth quarter of 2005, and first quarter of 2006. The first program expired on June 30, 2006, the second program expired on August 31, 2006, and the third program expired on September 30, 2006. As of September 30, 2006 and December 31, 2005, the balance of the liabilities for these voucher programs totaled approximately \$262,000 and \$105,000, respectively.



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## **Table of Contents**

### *Voucher Rebate Program for ANTARA*

During the third quarter of 2006, we initiated a voucher rebate program whereby we offered a point-of-sale rebate to retail consumers. We have accounted for this program in accordance with EITF No. 01-09. The liabilities we recorded for this voucher rebate program were estimated based upon the historical rebate redemption rates for the similar completed programs by other pharmaceutical companies. This program expires on December 31, 2006. As of September 30, 2006, the balance of the liabilities for this voucher program totaled approximately \$339,000.

### **Clinical Trial Expense Accrual**

Our clinical development trials related to FACTIVE are primarily performed by outside parties. At the end of each accounting period, we estimate both the total cost and time period of the trials and the percent completed as of that accounting date. We also adjust these estimates when final invoices are received. For the nine months ended September 30, 2006 and the year ended December 31, 2005, the Company adjusted its accrual for clinical trial expenditures to reflect its most current estimate of liabilities outstanding to third parties. However, the possibility exists that the timing or cost of the clinical trials might be longer or shorter and cost more or less than estimated and that the associated financial adjustments would be reflected in future periods.

### **Inventories**

Inventories are stated at the lower of cost or market with cost determined under the average cost method. Products are removed from inventory and recognized as cost of goods sold on an average cost basis. For FACTIVE, inventories consist of raw material in powder form and work-in-process of approximately \$5,444,000 and \$9,770,000, and FACTIVE finished tablets of approximately \$3,786,000 and \$4,417,000, as of September 30, 2006 and December 31, 2005, respectively. For ANTARA, inventories consist of raw material and work-in-process of approximately \$3,018,000 and \$0, and ANTARA finished capsules of approximately \$2,653,000 and \$0, as of September 30, 2006 and December 31, 2005, respectively.

On a quarterly basis, we analyze our inventory levels, and write down inventory and marketing samples that have become obsolete, have a cost basis in excess of its 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. At September 30, 2006 and December 31, 2005, there was approximately \$1,142,000 and \$2,072,000, in FACTIVE sample product to be used for FACTIVE marketing programs and approximately \$498,000 and \$0, respectively, in ANTARA samples product to be used for ANTARA marketing programs. These are classified as an other current asset in the consolidated balance sheet.

### **Long-Lived Assets**

We follow the provisions of SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS No. 144). Under SFAS 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.

We also follow the provisions of SFAS No. 142, *Goodwill and Other Intangible Assets*, (SFAS No. 142). Under SFAS 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 with our book value, including goodwill. 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 September 30, 2006, we do not believe that any of our long-lived assets, goodwill, and other intangible assets are impaired.

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**Table of Contents****Stock-Based Compensation**

Effective January 1, 2006, we adopted SFAS No. 123(R), 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 nine months ended September 30, 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 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. Prior to the adoption of SFAS No. 123R, we accounted for our employee share-based arrangements under APB No. 25. Under the modified prospective adoption method, the results for prior periods are not restated.

*Stock Plans*

We grant stock to key employees and consultants under our 1991, 1993, 1995 and 1997 Stock Option Plans, as well as the 2001 Incentive Plan. The Stock Option and Compensation Committee of the Board of Directors determines the purchase price and vesting schedule applicable to each option grant. As of September 30, 2006, there are no shares reserved for future grants under the 1991, 1993, 1995 and 1997 Plans. The 2001 Incentive Plan provides for the grant of non-qualified stock options, incentive stock options, restricted stock, stock appreciation rights, unrestricted stock, deferred stock, and cash performance awards. Generally, options granted to employees vest based on service conditions over a two to four year time period and options granted to non-employees vest based on service conditions over a one to three year time period, all of which have graded vesting. In addition, the requisite service period is generally equal to the vesting term. All options granted to both employees and non-employees have a contractual term of ten years from date of grant and generally, the exercise price of the stock options equals the fair market value of our common stock. Our 2001 Incentive Plan also provides for awards of nontransferable shares of restricted common stock which are subject to forfeiture. All shares of restricted stock are time vested which is generally over two years. Generally, the fair value of each restricted stock grant is equal to the market price of our stock at the date of grant. Certain option and restricted stock awards provide for accelerated vesting if there is a change in control.

*Employee Stock Purchase Plan*

We also have an Employee Stock Purchase Plan (ESPP) under which eligible employees may contribute up to 15% of their earnings toward the semi-annual purchase of our common stock. The employees purchase price is 85% of the fair market value of the common stock at the time of grant of option or the time at which the option is deemed exercised, whichever is less. The most recently completed offering period began January 1, 2006 and ended on June 30, 2006; therefore, January 1, 2006 is considered the grant date for the purposes of recognizing the stock-based compensation expense for this offering period. We project the estimated contributions at the beginning of the period and uses the Black-Scholes-Merton option-pricing model in order to determine the estimated fair value of the stock to be issued. At the end of the offering period, we adjust the estimated contributions to actual. Under Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees (APB 25), we were not required to recognize stock-based compensation expense for the cost of stock options or shares issued under our ESPP because the ESPP was determined to be noncompensatory. Upon adoption of SFAS 123R, we began recording stock-based compensation expense related to the ESPP.

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 volatility is determined exclusively on historical volatility data of our common stock beginning with our merger with Genesoft in February 2004 through the month of grant. Our expected volatility for the nine month period ended September 30, 2006 was between 52.14% and 61.62%. 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 term assumption. Our risk-free interest rate for the nine month period ended September 30, 2006 was between 4.35% and 5.07%. Our expected life using this method for the nine month period ended September 30, 2006 was 5.00 to 6.25 years. We have not paid and do not expect to pay any dividends and, as a result, our dividend yield is assumed to be 0%.

**Table of Contents**

The adoption of SFAS No. 123R increased our three and nine months ended September 30, 2006 operating loss, net loss, and cash flows from operating activities by \$1,020,000 and \$3,063,000, respectively, and basic and diluted net loss per share by \$0.01 and \$0.03, 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. Additionally, we eliminated the January 1, 2006 deferred compensation balance against additional paid-in capital upon adoption of SFAS No. 123R.

Our policy is to recognize compensation cost for awards for only service conditions and graded vesting using the straight-line method. 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. SFAS 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 23.24% to all unvested options as of September 30, 2006. This analysis will be re-evaluated quarterly 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.

As of September 30, 2006, we estimate there was approximately \$6,230,000 of total unrecognized compensation costs related to unvested share based awards. These cost are expected to be recognized over a weighted average remaining requisite service period of 1.7 years. We expect approximately 2,812,000 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.

**Results of Operations**

***Three Month Periods Ended September 30, 2006 and September 30, 2005***

***Revenues***

Total revenues increased 108% to approximately \$12,362,000 for the three month period ended September 30, 2006 from approximately \$5,941,000 for the three month period ended September 30, 2005.

Product sales increased 74% to \$8,308,000 for the three month period ended September 30, 2006 from \$4,778,000 for the three month period ended September 30, 2005. This increase was primarily related to the acquisition of ANTARA® 130 mg (fenofibrate) capsules which resulted in approximately \$4,256,000 in product sales.

Co-promotion revenue increased 199% to \$3,474,000 for the three month period ended September 30, 2006 from \$1,161,000 for the three month period ended September 30, 2005 primarily due to a \$1,800,000 payment from Auxilium Pharmaceuticals in August 2006 in connection with the termination of the co-promotion arrangement.

Biopharmaceutical/Other revenues increased to \$580,000 for the three month period ended September 30, 2006 from \$2,000 for the three month period ended September 30, 2005 primarily due to an up-front license payment related to Pfizer Mexico which is recognized over the term of our obligation under the agreement which is 18 months, a milestone payment related to the approval to distribute and sell FACTIVE tablets in Mexico and the achievement of a milestone by the genomics business we sold to Agencourt Bioscience in 2004. We expect our revenues related to both the biopharmaceutical alliances and genomics services to be minimal in the future.

***Costs and Expenses***

Total costs and expenses increased 21% to approximately \$32,448,000 for the three month period ended September 30, 2006 from approximately \$26,816,000 for the three month ended September 30, 2005.

Cost of product sales increased by 226% to approximately \$6,573,000 for the three month period ended September 30, 2006 from \$2,018,000 for the three month period ended September 30, 2005. The gross margin on product sales was approximately 21% and 58% for the three month periods ended September 30, 2006 and 2005. The decrease in margin during the three month period ended September 30, 2006 is due to higher volume of FACTIVE tablets shipped to Pfizer Mexico, which resulted in lower FACTIVE margins, increased royalty rates to LG related to FACTIVE, increased costs associated with the costs of product sold related to the write up of ANTARA inventory in purchase accounting of approximately \$357,000, an increase in the FACTIVE rebates redeemed and \$579,000 recorded as a provision of obsolete inventory recorded in the three month period ended September 30, 2006. In addition, included in the cost of product sales is approximately \$1,191,000 of amortization of intangible assets associated with FACTIVE for the three month periods ended September 30, 2006 and 2005 and approximately \$526,000 and \$0, respectively, of amortization of intangible assets associated with ANTARA for the three month periods ended September 30, 2006 and 2005.

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The gross margin excluding amortization of intangible assets was approximately 42% and 83% for the three month periods ended September 30, 2006 and 2005.

**Table of Contents**

Research and development expenses include internal research and development expenses as well as clinical development costs and expenses. Research and development expenses primarily consist of salaries and related expenses for personnel. Other research and development expenses include fees paid to consultants and outside service providers, information technology costs and facilities costs. Research and development expenses increased 52% to approximately \$4,281,000 for the three month period ended September 30, 2006 from approximately \$2,814,000 for the three month period ended September 30, 2005. The increase in research and development expenses is due to an increase of approximately \$1,444,000 related to the FACTIVE ABS sNDA and the FDA Advisory Committee meeting in the current quarter and an increase of approximately \$23,000 in stock based compensation expense.

Selling and marketing expenses decreased 12% to approximately \$17,215,000 for the three month period ended September 30, 2006 from \$19,460,000 for the three month period ended September 30, 2005. The decrease in selling and marketing expenses is due to a decrease of approximately \$2,012,000 in sales and marketing personnel and related costs, decreased sample expenses of approximately \$1,232,000, offset by an increase in other selling and marketing costs of approximately \$651,000 relating to the promotion of FACTIVE, TESTIM and ANTARA and an increase in stock-based compensation expense of approximately \$348,000.

General and administrative expenses increased 73% to \$4,379,000 for the three months period ended September 30, 2006 from \$2,524,000 for the three month period ended September 30, 2005. The increase is due to the recognition of approximately \$614,000 in additional stock based compensation expense related to the adoption of FAS 123R, increased license fees of approximately \$542,000 primarily attributable to our agreement granting Abbott Laboratories the rights to sell FACTIVE tablets in Canada and approval to distribute FACTIVE tablets in Mexico by Pfizer, increased allowance for a receivable of approximately \$172,000 related to a government overhead audit in connection with Genesoft, increase in general and administrative personnel and related costs of approximately \$441,000, and an increase in other general and administrative expenses of approximately \$86,000.

***Other Income and Expense***

Interest income decreased 4% to approximately \$842,000 for the three month period ended September 30, 2006 from approximately \$877,000 for the three month period ended September 30, 2005 reflecting lower overall cash balances offset by higher interest rate yields on investments.

Interest expense increased 37% to approximately \$2,807,000 for the three month period ended September 30, 2006 from approximately \$2,055,000 for the three month period ended September 30, 2005. For the period ended September 30, 2006, interest expense primarily consisted of approximately \$1,366,000 related to the \$153 million of senior convertible notes issued in the second quarter of 2004, \$313,000 related to the issuance of \$22 million of convertible notes issued in connection with the Genesoft merger, \$207,000 related to amortization of deferred financing costs, \$82,000 of non-cash interest expense related to the facility lease liability, along with \$293,000 of interest expense on the note payable to Paul Capital Partners (PRF) and \$546,000 of revenue interest to PRF.

***Nine Month Periods Ended September 30, 2006 and September 30, 2005******Revenues***

Total revenues increased significantly to approximately \$27,888,000 for the nine month period ended September 30, 2006 from approximately \$14,123,000 for the nine month period ended September 30, 2005.

Product sales increased 61% to approximately \$20,176,000 for the nine month period ended September 30, 2006 from \$12,495,000 for the nine month period ended September 30, 2005. The increase was primarily related to the acquisition of ANTARA 130 mg (fenofibrate) capsules which resulted in approximately \$4,256,000 in product sales and increased shipment of FACTIVE tablets of approximately \$3,425,000.

Co-promotion revenues increased significantly to approximately \$6,890,000 for the nine month period ended September 30, 2006 from \$1,531,000 for the nine month period ended September 30, 2005 primarily due to the fact that we initiated our co-promotion of TESTIM in May 2005, higher gross profits related to increased TESTIM scripts and also due to a \$1,800,000 payment from Auxilium Pharmaceuticals in August 2006 in connection with the termination of the co-promotion arrangement.

Biopharmaceutical/Other revenues increased significantly to \$822,000 for the nine month period ended September 30, 2006 from \$96,000 for the nine month period ended September 30, 2005 primarily due to the achievement of a milestone by the genomics business we sold to Agencourt Bioscience in 2004 and the recognition of revenues in connection with various milestone achievements related to Pfizer Mexico upon the regulatory approval to distribute and sell FACTIVE tablets in Mexico and an up-front payment from Pfizer Mexico which is recognized over the term of our obligation under the agreement. We expect our revenues related to both the biopharmaceutical alliances and genomics services to be minimal in the future.





**Table of Contents*****Costs and Expenses***

Total costs and expenses increased 2% to approximately \$88,901,000 for the nine month period ended September 30, 2006 from approximately \$86,828,000 for the nine month period ended September 30, 2005.

Cost of product sales increased 85% to approximately \$11,808,000 for the nine month period ended September 30, 2006 from \$6,391,000 for the nine month period ended September 30, 2005. The gross margin on product sales was approximately 41% and 49% for the nine months ended September 30, 2006 and 2005, respectively. The decrease in margin during the nine months ended September 30, 2006 is due to a slightly lower volume of FACTIVE tablets shipped to wholesalers, a provision of obsolete inventory of \$986,000 and increased costs associated with the costs of product sold related to the write up of ANTARA inventory in purchase accounting of approximately \$357,000. In addition, included in the cost of product sales is approximately \$3,573,000 of amortization of intangible assets associated with FACTIVE for each of the nine month periods ended September 30, 2006 and 2005 and approximately \$526,000 and \$0, respectively, of amortization of intangible assets associated with ANTARA for the nine month periods ended September 30, 2006 and 2005. The gross margin excluding amortization of intangible assets was approximately 62% and 77% for the nine month periods ended September 30, 2006 and 2005.

Research and development expenses decreased 20% to approximately \$10,415,000 for the nine month period ended September 30, 2006 from approximately \$13,009,000 for the nine month period ended September 30, 2005. The decrease in research and development expenses is due to a reduction of approximately \$3,028,000 related to the completion of the FACTIVE 5-day clinical study in 2005, a decrease of approximately \$721,000 in stock based compensation expense, a decrease of approximately \$639,000 in research and development personnel and related costs, offset by increases of approximately \$1,444,000 in research and development expenses related to additional costs associated with the FACTIVE ABS sNDA and the FDA Advisory Committee meeting and an increase of approximately \$350,000 in technology license fee.

Selling and marketing expenses decreased 4% to approximately \$54,897,000 for the nine month period ended September 30, 2006 from approximately \$57,278,000 for the nine month period ended September 30, 2005. The decrease in selling and marketing expenses is due to a decrease of approximately \$2,131,000 in sales and marketing personnel and related costs, decreases of approximately \$1,373,000 in sample expenses, offset by an increase of approximately \$71,000 in other selling and marketing costs relating to the promotion of FACTIVE, TESTIM and ANTARA and an increase of approximately \$1,052,000 in stock-based compensation expense.

General and administrative expenses increased 16% to approximately \$11,781,000 for the nine month period ended September 30, 2006 from approximately \$10,150,000 for the nine month period ended September 30, 2005. The increase is due to the recognition of approximately \$1,718,000 in additional stock based compensation expense related to the adoption of FAS 123R, increased license fees of approximately \$611,000 primarily attributable to our agreement granting Abbott Laboratories the rights to sell FACTIVE tablets in Canada and approval to distribute FACTIVE tablets in Mexico by Pfizer, increased allowance for a receivable of approximately \$172,000 related to a government overhead audit in connection with Genesoft, an increase of approximately \$783,000 in general and administrative personnel and related costs, and increased legal costs of approximately \$347,000 related to business development expenses. These increases were offset by a \$2,000,000 milestone payment made to LG in 2005, with no comparable expense in 2006.

***Other Income and Expense***

Interest income decreased 7% to approximately \$2,439,000 for the nine month period ended September 30, 2006 from approximately \$2,628,000 for the nine month period ended September 30, 2005 reflecting lower overall cash balances offset by higher interest rate yields on investments.

Interest expense increased 11% to approximately \$6,889,000 for the nine month period ended September 30, 2006 from \$6,196,000 for the nine month period ended September 30, 2005. For the period ended September 30, 2006, interest expense primarily consisted of approximately \$4,025,000 related to the \$153 million of senior convertible notes issued in the second quarter of 2004, \$925,000 related to the issuance of \$22 million of convertible notes issued in connection with the Genesoft merger, \$615,000 related to amortization of deferred financing costs, \$480,000 of non-cash interest expense related to the facility lease liability, along with \$293,000 of interest expense on the note payable to PRF and \$546,000 of revenue interest to PRF.

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**Table of Contents**

For the nine month period ended September 30, 2006, we recorded a gain of approximately \$1,617,000 related to a milestone achievement pertaining to the sale of our investment in Agencourt Bioscience. For the nine month period ended September 30, 2005, we recorded a gain on the disposition of marketable securities of approximately \$2,162,000 in exchange for our ownership of common stock of Agencourt Bioscience Corporation, which was recently acquired by Beckman Coulter in a cash transaction.

**Liquidity and Capital Resources**

Our primary sources of cash have been from the sale of debt and equity securities, product discovery alliances, the sale of FACTIVE tablets and ANTARA capsules and co-promotion revenues based on the sale of TESTIM. The co-promotion agreement was terminated on August 31, 2006.

As of September 30, 2006, we had total cash, cash equivalents, restricted cash and short-term marketable securities of approximately \$52,035,000, which includes approximately \$9,265,000 in restricted cash. We will need to raise additional capital in the future to fund our operations. In order to facilitate the raising of additional funds, we have filed a shelf-registration statement with the SEC that allows us to sell up to \$100 million of common stock, warrants and/or debt securities. We believe that, under our current rate of investment in development and commercialization programs, our existing capital resources are adequate to support operations through the first half of 2007. 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 costs in an effort to build an effective sales and marketing organization to commercialize FACTIVE tablets and co-promote TESTIM, expand the medical/development organization to support additional FACTIVE development and commercialization, support the development of Ramoplanin and to build the infrastructure necessary to support these expansions. We expect expenses in the sales and marketing areas to increase as we continue to commercialize FACTIVE, integrate the ANTARA product and seek to grow our sales.

**Cash Flows**

Our operating activities used cash of approximately \$56,286,000 and \$78,636,000 for the nine month periods ended September 30, 2006 and 2005, respectively. Cash used in our operating activities for nine month period ended September 30, 2006 was primarily a result of our net loss of approximately \$63,786,000, increases in accounts receivable of approximately \$3,356,000 primarily resulting from acquisition of ANTARA trade receivables, increases in inventory of approximately \$1,700,000, decreases in clinical trial expense accrual of approximately \$435,000 related to the FACTIVE post marketing studies, gain on disposition of investment of approximately \$1,617,000, accrued facilities impairment charge of approximately \$2,167,000 related to our west coast facility, and accrued restructuring charge of approximately \$904,000 related to our prior facility in Waltham, Massachusetts. These uses of cash were partially offset by increases in accounts payable of \$1,288,000, accrued expenses and other current liabilities of approximately \$3,120,000 related to higher accrued sales reserves and allowances related to a sample card promotional program and ANTARA rebate programs, higher deferred revenue of approximately \$444,000, higher other long-term liabilities of approximately \$1,071,000, decreases in interest receivable of approximately \$236,000 due to lower overall cash balances and lower prepaid expenses and other current assets of approximately \$1,321,000 related to decreased prepaid marketing costs for the nine month period ended September 30, 2006. Offsetting our operating uses of cash were non-cash depreciation and amortization expenses of approximately \$4,664,000, stock-based compensation of \$3,110,000, provision for excess and obsolete inventories of approximately \$986,000, and provision for bad debts of approximately \$344,000, as well as non-cash interest expenses of approximately \$1,095,000.

Cash used in our operating activities for nine month period ended September 30, 2005 was primarily a result of our net loss of approximately \$71,517,000, increases in inventory of approximately \$5,629,000 due to anticipated increased demand of FACTIVE tablets in the second half of the year, gain on sale of fixed assets of approximately \$51,000, and gain on disposition of investment of approximately \$2,163,000, as well as decreases in accounts payable of approximately \$4,432,000, deferred revenues of approximately \$1,302,000 related to our initial stocking incentive program, accrued facilities impairment charge of approximately \$2,378,000 related to our west coast facility, and accrued restructuring charge of approximately \$907,000 related to our prior facility in Waltham, Massachusetts and accrued expenses and other current liabilities of approximately \$5,517,000. These uses of cash were partially offset by increases in clinical trial expense accrual of approximately \$1,432,000 related to the clinical trial of FACTIVE for the 5-day treatment of CAP and post marketing studies, and other long-term liabilities of approximately \$905,000 related to the accruing of interest for the \$22 million convertible note. Offsetting the uses of cash were also decrease of prepaid expenses and other current assets of approximately \$5,203,000, interest receivable of \$982,000 and accounts receivable of \$409,000 as well as non-cash depreciation and amortization expenses of approximately \$4,035,000, stock-based compensation of \$1,000,000 and non-cash interest of approximately \$1,294,000.

**Table of Contents**

Our investing activities used cash of approximately \$70,905,000 for the nine month period ended September 30, 2006 and provided cash of approximately \$85,116,000 for the nine month period ended September 30, 2005, respectively. Cash used by our investing activities for the nine month period ended September 30, 2006 was primarily related to the acquisition of ANTARA of approximately \$77,513,000, and increases in other assets of approximately \$284,000. These uses of cash were partially offset by proceeds for maturities of marketable securities of approximately \$2,696,000, decreases in restricted cash of approximately \$2,465,000, proceeds for the disposition of investment of approximately \$1,617,000, and proceeds from notes receivable of approximately \$271,000. Cash provided by our investing activities for the nine month period ended September 30, 2005 was primarily related to proceeds from maturities of marketable securities of approximately \$83,489,000, proceeds of approximately \$2,388,000 related to the disposition of Agencourt stock upon its acquisition by Beckman Coulter as well as decreases in restricted cash of approximately \$2,587,000 related to the payment of convertible note interest, proceeds from notes receivable of approximately \$267,000, and proceeds from the sale of property and equipment of approximately \$225,000. Cash provided by investing activities were partially offset by the issuance of notes receivable of approximately \$2,740,000 related to a deposit required in order to lease vehicles for the sale representatives, net purchases of property and equipment of approximately \$1,051,000, and increases in other assets of approximately \$49,000.

Our financing activities provided cash of approximately \$104,342,000 for the nine month period ended September 30, 2006, primarily due to the issuance of 18,035,216 shares of common stock in connection with the completion of a private placement which generated net proceeds of approximately \$33,478,000, proceeds of \$20,000,000 from the issuance of notes in connection with the financing of the ANTARA acquisition, proceeds of \$40,000,000 from assignment of revenue interest, net proceeds of approximately \$9,958,000 from the issuance of 11,111,111 shares of common stock in connection with financing the acquisition of ANTARA, exercise of 715,648 stock options of approximately \$166,000 and proceeds of approximately \$740,000 from the issuance of 631,896 shares of stock under the employee stock purchase plan.

Our financing activities provided cash of approximately \$671,000 for the nine month period ended September 30, 2005, primarily due to proceeds from exercise of 1,004,068 stock options of approximately \$546,000 and proceeds from the issuance of 160,800 shares of stock under the employee stock purchase plan of \$417,000 offset by payments of current portion of long-term obligations of approximately \$292,000.

At December 31, 2005, we had net operating loss carryforwards of approximately \$319,000,000 and \$165,311,000 available to reduce federal and state taxable income respectively, if any. In addition, we also had tax research credit carryforwards of approximately \$9,636,000 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%. Additionally, certain of our losses have begun to expire due to time, not limitations.

*Our Outstanding Debt Obligations*

In the quarter ended June 26, 2004, we issued \$152,750,000 in principal amount of our 3.5% senior convertible promissory notes due April 2011. These notes are convertible into shares of our common stock at the option of the holders at a conversion price of approximately \$6.64 per share. We may not elect to redeem the notes before May 10, 2010. After this date, we can redeem all or a part of the notes for cash at a price equal to 100% of the principal amount of the notes to be redeemed plus accrued and unpaid interest. Upon the occurrence of a termination of trading of our common stock or a change of control transaction in which substantially all of our common stock is exchanged for consideration other than common stock that is listed on a U.S. national securities exchange or market (such as NASDAQ), holders of these 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. In addition, in the case of a change of control transaction in which all of the consideration paid for our common stock consists of cash, we may have an obligation to pay an additional make-whole premium to the note holders based on a formula set forth in the indenture.

On February 6, 2004, in connection with our merger with Genesoft, we issued \$22,309,647 in principal amount of our 5% convertible five year promissory notes which were recorded in investing activities as cash flows related to acquisition. These notes are convertible into our common stock at the option of the holders, at a conversion price of approximately \$6.64 per share (subject to anti-dilution and other adjustments). In addition, we have the right to force conversion if the price of our common stock closes above 150% of the then effective conversion price for 15 consecutive trading days. At the closing of the merger, the holders of these notes also received an aggregate of 4,813,547 shares of our common stock representing the payment of accrued interest and related amounts on certain outstanding notes previously issued to such holder by Genesoft. On February 6, 2004, in conjunction with the merger with Genesoft, we sold 16.8 million shares of our common stock at \$5.25 per share resulting in proceeds received of approximately \$81.0 million, net of issuance costs.

**Table of Contents***Other Financial Arrangements*

To finance the acquisition of ANTARA in August 2006, we, together with our 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 (PRF), 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. We entered into the Revenue Interests Assignment Agreement (the Revenue Agreement), pursuant to which we sold to PRF the right to receive specified royalties on Guardian II's and Oscient's net sales in the United States (and the net sales of their respective affiliates and licensees) of the ANTARA products and FACTIVE tablets until December 31, 2016. The royalty payable to PRF 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 PRF exceed \$100 million, the royalties become nominal.

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), PRF has the right to require us to repurchase from PRF its royalty interest at a price in cash which equals the greater of (a) a specified multiple of cumulative payments made by PRF under the Revenue Agreement less the cumulative royalties previously to PRF; or (b) the amount which will provide PRF, when taken together with the royalties previously paid, a specified rate of return (the Put/Call Price). Upon a bankruptcy event, we are automatically required to repurchase the PRF royalty interest at the Put/Call Price. In the event of a change of control of Oscient, we have the right to repurchase the PRF royalty interest for an amount equal to the Put/Call Price.

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, we have the right, but not the obligation, to reduce the royalty percentages due under the Revenue Agreement to PRF by 50% by paying PRF a price in cash which will provide PRF, 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, we have the right, but not the obligation, to repurchase the PRF royalty interest at a price in cash which will provide PRF, when taken together with the royalties previously paid, a specified rate of return.

Guardian II entered into a Note Purchase Agreement (the Note Purchase Agreement) with PRF 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) we issue to PRF, 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 \$0.8680, with an exercise price of \$.8680 per share. If we exercise such option, the number of shares subject to the warrant issuable to PRF would be between 2,304,147 shares and 2,940,230 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, we 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 shall become immediately due and payable.

Subject to the Revenue Agreement and the Note Purchase Agreement, without the prior written consent of PRF, we have agreed not 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 its material rights under existing agreements that would adversely affect PRF'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 PRF entered into a Security Agreement (the Security Agreement) under which Guardian II granted to PRF 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 PRF also entered into a Common Stock and Warrant Purchase Agreement (the Stock and Warrant Purchase Agreement), pursuant to which, in exchange for \$10 million, Oscient sold to PRF 11,111,111 shares (the Shares) of the Common Stock, at a price of \$0.90 per share (the Private Placement) and issued PRF a warrant (the



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## **Table of Contents**

Warrant ) to purchase 2,304,147 shares of Common Stock (the Warrant Shares ) at an exercise price of \$0.8680 per share. The Warrant is exercisable for seven years from the date of closing. The Warrant contains a cashless exercise option and penalties if Oscient does not deliver the applicable amount of Warrant Shares within three trading days of exercise of a Warrant by PRF. The Warrant also contains provisions providing that, at PRF's election, Oscient must re-purchase the Warrant from PRF upon a sale of the Company in which the consideration for such sale is solely cash.

We agreed pursuant to the Stock and Warrant Purchase Agreement to elect one person designated by PRF to our Board of Directors following the closing and to continue to nominate one person designated by PRF for election to our Board of Directors by our shareholders. The director designated by PRF shall resign and we shall no longer be required to nominate a director designated by PRF upon the later of the following events: (1) if PRF ceases to own at least five percent of the our Common Stock or securities convertible into our Common Stock; (2) if we owe PRF less than \$5,000,000 under the Note pursuant to the Note Purchase Agreement; (3) the cumulative payments to PRF made by us under the terms of the Revenue Agreement first exceed 250% of the consideration paid to us by PRF; or (4) if the amounts due by us pursuant to the Revenue Agreement cease to be due. If at any time PRF's designee is not elected to our Board of Directors, PRF's designee will have a right to participate in all meetings of our Board of Directors in a nonvoting observer capacity.

### **Contractual Obligations**

To finance the acquisition of ANTARA in August 2006, we, together with our wholly-owned subsidiary Guardian II Acquisition Corporation, entered into several financing agreements with Paul Royalty Fund Holdings II, LP, an affiliate of Paul Capital Partners, 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. The terms and conditions of the Revenue Interest Assignment Agreement, the Note Purchase Agreement and the Common Stock and Warrant Purchase Agreement are reviewed in detail above under the Section entitled *Liquidity and Capital Resources Cash Flows*.

### **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, 2005. There have been no material changes in information affecting our market risk since the end of the fiscal year ended December 31, 2005. Our Annual Report on Form 10-K was filed with the Securities and Exchange Commission on March 10, 2006.

### **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.

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.

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**Table of Contents**

**PART II OTHER INFORMATION**

**ITEM 1: LEGAL PROCEEDINGS**

None

**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**

**We have a history of significant operating losses and expect these losses to continue in the future.**

We have experienced significant operating losses each year since our inception and expect these losses to continue for the foreseeable future. We had a net loss of approximately \$63,786,000 for the nine months ended September 30, 2006 and had an accumulated deficit of approximately \$401,214,000. The losses have resulted primarily from 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 of FACTIVE tablets. These costs have exceeded our revenues which to date have been generated principally from sales of FACTIVE, co-promotion revenues based on the sale of TESTIM gel, collaborations, government grants and sequencing services.

We anticipate that we will incur additional losses in the current year and in future years and cannot predict when, if ever, we will achieve profitability. These losses are expected to continue and potentially increase as we continue significant levels of expenditures, principally in the sales and marketing area as we seek to grow sales of FACTIVE tablets and ANTARA capsules (including efforts to successfully integrate of ANTARA) and as we seek to acquire additional 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 will be very dependent on the commercial success of FACTIVE and ANTARA.**

FACTIVE tablets and ANTARA capsules 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.

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. ANTARA is approved by the FDA to treat hypercholesterolemia (high blood cholesterol) and hypertriglyceridemia (high triglycerides) in combination with a healthy diet. The commercial success of FACTIVE and ANTARA 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. If FACTIVE and ANTARA are not commercially successful, we will have to find additional sources of funding or curtail or cease operations.

**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 and/or FACTIVE.**

The intellectual property rights of biopharmaceutical companies, including us, are generally uncertain and involve complex legal, scientific and factual questions. Our success in developing and commercializing biopharmaceutical 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 biopharmaceutical industry. We may 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 biopharmaceutical 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. We may become involved in patent litigation against third parties to enforce our patent rights, to invalidate patents held by such third parties, or to defend against such claims. 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



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## **Table of Contents**

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 without a license from a third party. We may not be able to obtain such a license on commercially acceptable terms, or at all.

For instance, we are aware of United States patents that are owned by third parties that may be construed to encompass ANTARA. However, we believe that, if these patents were asserted against us, it is likely that we would not be found to infringe any valid claim 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 or enforceability 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 could 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.

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

We believe our existing funds and anticipated cash flows from operations would be sufficient to support our current plans through the first half of 2007. We will likely raise additional capital in the future to fund our operations, to support our sales and marketing activities, fund clinical trials and other research and development activities, and other potential commercial or development opportunities. We may seek funding through additional public or private equity offerings, debt or other strategic financings or agreement with customers or vendors. In order to facilitate the raising of additional funds, we have filed a shelf registration statement that allows us to sell up to \$100,000,000 of our common stock, warrants and debt securities. Our ability to raise additional capital, however, will be heavily influenced by, among other factors, the investment market for biopharmaceutical companies and the progress of the FACTIVE, ANTARA and Ramoplanin commercial and clinical development programs. 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 fund raising could dilute the ownership interests of our stockholders.**

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 outstanding shares of our common stock in order to fund our operating plans, potentially requiring a stockholder vote. In addition, we may have to sell securities at a discount to the prevailing market price, resulting in further dilution to our stockholders.

### **We will need to continue to develop marketing and sales capabilities to successfully commercialize FACTIVE tablets, ANTARA capsules and our other product candidates, including effectively integrating the ANTARA product into our commercial operations.**

FACTIVE tablets and ANTARA capsules are the first two FDA approved products which we own and promote. To date, we still have limited marketing and sales experience. The launch of FACTIVE occurred in September of 2004, and we recently acquired the rights to ANTARA in August 2006. The continued development of these marketing and sales capabilities, including the expansion of our sales force, will require significant expenditures, management resources and time.

The integration of the ANTARA product and continued development of our marketing and sales capabilities with respect to this new line of product, including the possibility of expansion of our sales force, will require significant expenditures, management resources and time. Failure to successfully integrate ANTARA and establish sufficient sales and marketing capabilities in a timely and regulatory compliant manner may adversely affect our ability to assume and continue to grow the ANTARA brand and related product sales.

### **Our product and product candidates will 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 branded versions of fenofibrate could reduce our net sales of ANTARA and adversely impact our revenues. The primary competition for ANTARA for the treatment of dyslipidemias is Tricor 145 mg, a product manufactured by Abbott Laboratories, which accounted for approximately 94% of U.S. fenofibrate sales for the twelve month period ended September 30, 2006. ANTARA also competes with Triglide, a fenofibrate marketed by Sciele Pharma, Inc., which accounted for approximately 0.86% of U.S. fenofibrate sales for the twelve

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month period ended September 30, 2006. Additionally, several generic versions fenofibrate in varying strengths are also available for the treatment of dyslipidemias. In May 2005, Teva Pharmaceutical Industries, Ltd. obtained final FDA approval to market a generic version of Abbott Laboratories 160 mg Tricor tablet (which is no longer marketed or sold), which contains the same active pharmaceutical ingredient as ANTARA 130 mg capsules. In January 2006, Cipher Pharmaceuticals, Inc. obtained final FDA approval to market a 150 mg strength of fenofibrate.

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## Table of Contents

There are also several non-fenofibrate FDA approved products with similar indications as ANTARA which could compete with ANTARA. Reliant Pharmaceuticals, Inc., for example, markets Omacor, an omega-3 fatty acid product used for the treatment of hypertriglyceridemia. Additionally, Kos Pharmaceuticals, Inc. markets Niaspan, an extended-release niacin product used to raise HDL as well as Advicor, a fixed-dose combination of niacin and simvastatin, used to treat mixed-lipid disorders.

We are also aware that LifeCycle Pharma A/S has a 120 mg fenofibrate product currently in development and submitted a new drug application to the FDA in October 2006. In addition, several companies may be developing fixed-dose combination products containing fenofibrate with HMG-CoA reductase inhibitors, such as simvastatin or atorvastatin, which may also compete with ANTARA. We are also aware of other Companies developing fenofibrate products. The marketing of generic fenofibrate products could result in 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 such as Levaquin® (levofloxacin), a product of Ortho-McNeil Pharmaceutical, Inc., and Cipro® (ciprofloxacin) and Avelox® (moxifloxacin), both products of Bayer Corporation as well as generic equivalents of Cipro;

macrolides such as Biaxin® (clarithromycin), a product of Abbott Laboratories and Zithromax® (azithromycin), a product of Pfizer Inc., as well as generic equivalents of both products;

Ketek® (telithromycin), a ketolide from Sanofi-Aventis Pharmaceuticals; and

penicillins such as Augmentin® (amoxicillin/clavulanate potassium), a product of GlaxoSmithKline, as well as generic equivalents of this product.

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 gone or will be going off patent at dates ranging from 2003 to 2015. As these competitors lose patent protection, their manufacturers will likely decrease their promotional efforts. However, makers 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 Vancocin® pulvules (vancomycin), a product marketed by ViroPharma Inc., and metronidazole, a generic product for treatment of this indication. We are also aware of at least eight companies with products in development for the treatment of CDAD. It is also possible that other companies are developing competitive products for this indication.

Many of our competitors have substantially greater capital resources, facilities 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.

**Our failure to acquire and develop additional product candidates or approved products will impair our ability to grow.**

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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 biopharmaceutical 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 upfront cash payments which could adversely affect our liquidity and/or accelerate our need to raise additional capital.

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## **Table of Contents**

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 cannot expand the indications for which we will market FACTIVE unless we receive FDA approval for each additional indication. Failure to expand these indications will limit the size of the commercial market for FACTIVE.**

In April 2003, FACTIVE tablets were approved by the FDA for the seven-day treatment of community-acquired pneumonia of mild to moderate severity (CAP) and the five-day treatment of acute bacterial exacerbations of chronic bronchitis (AECB). In our attempt to continue to develop the market for FACTIVE, we completed a clinical trial to demonstrate that a five-day course of FACTIVE for the treatment of mild to moderate CAP is as effective as the currently approved seven-day course of treatment. On September 21, 2006, we received an approvable letter from the U.S. Food and Drug Administration (FDA) for the supplemental New Drug Application (sNDA) seeking approval for the five-day treatment CAP with FACTIVE tablets. According to the letter, we are required to provide clarification and additional interpretation regarding certain data included in the application to assist the FDA in its evaluation. We recently delivered this additional information to the FDA. We cannot be certain whether additional data will be required or if the five-day CAP sNDA will ultimately be approved. If we are unsuccessful in expanding the approved indications for the use of FACTIVE, the size of the commercial market for FACTIVE will be limited.

**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 November 1 and March 31 as the incidence of respiratory tract infections, including CAP and AECB, tend 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.

**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.**

The testing, development and manufacturing and distribution of our products are subject to regulation by numerous governmental authorities in the U.S., Europe, Mexico and elsewhere. These regulations govern or affect the testing, manufacture, safety, labeling, storage, record-keeping, approval, distribution, advertising and promotion of FACTIVE, ANTARA, Ramoplanin and our other product candidates, as well as safe working conditions and the experimental use of animals. Noncompliance with any applicable regulatory requirements can result in refusal of the government to approve products for marketing, criminal prosecution and fines, recall or seizure of products, total or partial suspension of production, prohibitions or limitations on the commercial sale of products or refusal to allow the entering into of federal and state supply contracts. The U.S. government agencies include, but are not limited to, the FDA, the Office of Inspector General and the Department of Justice. Our corporate compliance program cannot 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.

The FDA and comparable governmental authorities have the authority to withdraw product approvals that have been previously granted. Currently, there is a substantial amount of congressional and administrative review of the FDA and the regulatory approval process for drug candidates in the U.S. As a result, there may be significant changes made to the regulatory approval process as well as post-marketing surveillance for drug safety in the U.S. In addition, the regulatory requirements relating to the manufacturing, testing, and promotion, marketing and distribution of our products may change in the U.S. or the other jurisdictions in which we may have obtained or be seeking regulatory approval for our products or product candidates. Such changes may increase our costs and adversely affect our operations.

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In addition, pharmaceutical companies are subject to extensive laws and regulations, including but not limited to the Prescription Drug Advertising and Marketing Acts, health care fraud and abuse laws, such as the Federal False Claims Act, the Federal Anti-kickback Statute, and other state and federal laws and regulations. In addition certain states such as California, Vermont, Minnesota and West Virginia have enacted their own regulations and guidelines relating to sales and marketing of pharmaceutical products while many other states have legislation pending relating to the same. While we have developed and implemented a corporate compliance program based upon what we believe to be current best practices, we cannot guarantee that this program will protect us from future lawsuits or investigations.

**Table of Contents**

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

restrictions on our products or manufacturing processes;

warning letters regarding promotional and marketing materials and activities;

withdrawal of FACTIVE, ANTARA or a product candidate from the market;

voluntary or mandatory recall of FACTIVE, ANTARA or a product candidate;

finances against us or our partners;

suspension or withdrawal of regulatory approvals for FACTIVE, ANTARA or a product candidate;

suspension or termination of any of our ongoing 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.

**We will depend on third parties to manufacture and distribute our products and product candidates, including FACTIVE tablets, ANTARA capsules and Ramoplanin.**

We do not have the internal capability to manufacture pharmaceutical products. Under our agreement with LG Life Sciences, LG Life Sciences manufactures the active pharmaceutical ingredient of FACTIVE and we use Patheon to produce the finished FACTIVE tablets. Currently, our only source of supply of bulk capsules of ANTARA is Ethypharm, and we have an agreement with Cardinal Health PTS, LLC to package finished ANTARA capsules. We cannot be certain that LG Life Sciences, Ethypharm, Patheon, Cardinal or future manufacturers will be able to deliver commercial quantities of product or that such deliveries will be made on a timely basis. The only source of supply for FACTIVE bulk drug substance is LG Life Sciences' facility in South Korea, and Patheon is currently our only source of finished FACTIVE tablets. The only source of supply for ANTARA capsules is Ethypharm. If these facilities are damaged or otherwise unavailable, we could incur substantial costs and delay in the commercialization of our products and our ability to generate revenue from FACTIVE and ANTARA may be adversely affected.

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Each of LG Life Sciences, Patheon, Ethypharm and Cardinal is subject to periodic and ongoing unannounced inspections by the FDA and other federal and state agencies to ensure strict compliance with current Good Manufacturing Practices, or cGMP, and other applicable government regulations. Future inspections may find deficiencies in the facilities or processes that may delay or prevent the manufacture or sale of FACTIVE or ANTARA.

Pursuant to our acquisition from Vicuron of worldwide rights to Ramoplanin, we assumed all responsibility for manufacture of Ramoplanin and are currently in discussions with potential third-party manufacturers for Ramoplanin in order to secure long term product supply. 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. Depending upon our discussions regarding a long-term source supplier for Ramoplanin or other product candidates, we could also incur substantial costs and delays in the further commercialization of such products. 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 produced by the new source or from the modified process is equivalent to the product used in any clinical trials that we had conducted.

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. No matter who manufactures the products, we will be subject to continuing obligations regarding the submission of safety reports and other post-market information.



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## **Table of Contents**

### **We will depend on third parties to manage our product supply chain for FACTIVE tablets and ANTARA capsules.**

We do not have the internal capability to perform product supply chain services including warehousing, inventory management and distribution of commercial and sample quantities of FACTIVE tablets and ANTARA capsules. We have an exclusive arrangement with Integrated Commercial Solutions, Inc. (ICS) to perform such supply chain services through the second quarter of 2007.

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 FACTIVE and ANTARA, in addition to loss of sales, we may also incur costs in establishing a new arrangement.

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

We sell FACTIVE and ANTARA to wholesale drug distributors who generally sell products to retail pharmacies and other institutional customers. We do not promote FACTIVE and ANTARA to these wholesalers, and they do not determine such products prescription demand. However, approximately 89% of our product shipments during the nine months ended September 30, 2006 were to only three wholesalers. Our ability to commercialize FACTIVE and/or ANTARA will depend, in part, on the extent to which we maintain adequate distribution of FACTIVE tablets ANTARA capsules via wholesalers, pharmacies and hospitals, as well as other customers. Although a majority of the larger wholesalers and retailers distribute and stock FACTIVE and ANTARA, 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 FACTIVE tablets or ANTARA capsules, the commercialization of FACTIVE and/or ANTARA and our anticipated revenues and results of operations could be adversely affected.

### **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, in February 2006, we entered into a sublicense arrangement with Pfizer, S.A. de C.V. (Pfizer Mexico), whereby Pfizer Mexico will commercialize FACTIVE tablets in Mexico in exchange for which Pfizer Mexico made an up-front payment, and will pay milestones upon obtaining certain regulatory approvals and sales goals as well as royalties on future sales. Additionally, in August 2006, we granted the commercialization rights to FACTIVE tablets in Canada to Abbott Canada. In exchange for those rights, Abbott Canada agreed to commercialize FACTIVE in Canada for a transfer price on product purchases and to make certain payments to us upon achievement of certain regulatory and sales milestones.

We may not be able to maintain our existing arrangements with respect to the commercialization of our existing products, FACTIVE and ANTARA, 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 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:

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

## **Table of Contents**

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.

**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.**

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. Prior clinical and preclinical trials for Ramoplanin were conducted by Vicuron and its licensees, from whom we acquired rights to Ramoplanin. We, or any third party with whom we may partner our rights to Ramoplanin, may not be able to complete future trials or make the filings within the timeframes we currently expect. If the trials or the filings are delayed, our business may be adversely affected.

We are currently conducting a Phase IV post-approval clinical trial relating to FACTIVE tablets in compliance with FDA requirements pursuant to the product's approval. Clinical trials may also be necessary to gain approval to market the product for the treatment of other indications.

We may not be able to demonstrate the safety and efficacy of FACTIVE in indications other than those for which it has already been approved or of our other products including Ramoplanin, in each case, 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.

The speed with which we are able to complete our clinical trials 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 infection rates 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; 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.

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.

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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 biopharmaceutical 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.

## **Table of Contents**

### **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 73 issued U.S. patents, approximately 85 pending U.S. patent applications, 146 issued foreign patents and approximately 199 pending foreign patent applications. These patents and patent applications primarily relate to (1) the chemical composition, use, and method of manufacturing FACTIVE, (2) pharmaceutical compositions, methods of their use and treatment, and methods of manufacturing ANTARA, (3) metalloenzyme inhibitors, their uses, their targets, (4) anti-infective compounds and their uses, and (5) the field of human and pathogen genetics. Our material patents are as follows:

U.S. Patent No. 4,800,079 granted January 24, 1989, relating to pharmaceutical compositions containing fenofibrate and methods of preparing the same; licensed from Ethypharm, S.A.; expiring August 10, 2007.

U.S. Patent No. 5,633,262 granted May 27, 1997, relating to quinoline carboxylic acid derivatives having 7-(4-amino-methyl-3-oxime) pyrrolidine substituent; licensed from LG Life Sciences; expiring June 15, 2015;

U.S. Patent No. 5,776,944 granted July 7, 1998, relating to 7-(4-aminomethyl-3-methyloxyiminopyrrolidin-1-yl)-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1, 8-naphthyridine-3-carboxylic acid; licensed from LG Life Sciences; expiring April 4, 2017;

U.S. Patent No. 5,869,670 granted February 9, 1999, relating to 7-(4-aminomethyl-3-methyloxyiminopyrrolidin-1-yl)-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1, 8-naphthyridine-3-carboxylic acid; licensed from LG Life Sciences; expiring June 15, 2015;

U.S. Patent No. 5,962,468 granted October 5, 1999, relating to 7-(4-aminomethyl-3-methyloxyiminopyrrolidin-1-yl)-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1, 8-naphthyridine-3 carboxylic acid; licensed from LG Life Sciences; expiring June 15, 2015;

U.S. Patent No. 6,340,689 granted January 22, 2002, relating to methods of using quinolone compounds against atypical upper respiratory pathogenic bacteria; licensed from LG Life Sciences; expiring September 14, 2019;

U.S. Patent No. 6,262,071 granted July 17, 2001, relating to methods of using antimicrobial compounds against pathogenic Mycoplasma bacteria; licensed from LG Life Sciences; expiring September 21, 2019;

U.S. Patent No. 6,331,550 granted December 18, 2001, relating to methods of using of quinolone compounds against anaerobic pathogenic bacteria; licensed from LG Life Sciences; expiring September 21, 2019;

U.S. Patent No. 6,455,540 granted September 24, 2002, relating to methods of use of quinolone compounds against anaerobic pathogenic bacteria; licensed from LG Life Sciences; expiring September 21, 2019;

U.S. Patent No. 6,723,734 granted April 20, 2004, relating to the salt of naphthyridine carboxylic acid derivative; licensed from LG Life Science; expiring March 20, 2018;

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U.S. Patent No. 6,803,376 granted October 12, 2004, relating to methods of use of quinolone compounds against pneumococcal pathogenic bacteria; licensed from LG Life Science; expiring September 21, 2019; and

U.S. Patent No. 7,101,574 granted September 5, 2006, relating to pharmaceutical compositions containing fenofibrate and methods of preparing the same; licensed from Ethypharm, S.A.; expiring August 20, 2020.

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 license agreement with LG Life Sciences, we obtained an exclusive license to develop and market gemifloxacin in certain territories. This license covers 18 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.PTO on our patent term extension application for U.S. Patent 5,776,944 extending its patent term 659 days to April 4, 2017. The U.S. patents are currently set to expire at various dates, ranging from 2018, in the case of the principal patents relating to FACTIVE tablets, to 2019.

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 includes two issued U.S. patents and several pending patent applications. These patents and applications include claims that relate to pharmaceutical compositions containing fenofibrate, the drug delivery technologies incorporated in ANTARA, methods of their uses and treatment, and methods of preparing the same. The U.S. patents are currently set to expire in 2007 and 2020.

## **Table of Contents**

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.

The patents to Ramoplanin, which we recently acquired from Pfizer Inc., include claims relating to methods of manufacturing Ramoplanin as well as methods increasing the yield of the active compound. We also have applications pending relating to various novel uses of Ramoplanin as well as a formulation 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 under the Hatch-Waxman Act in the U.S. and the ten years of market exclusivity in Europe available through the European Commission.

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;

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.

### **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.

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

*FACTIVE*

We have an exclusive license from LG Life Sciences to develop and market FACTIVE in North America and 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 and Vatican City. Under this



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**Table of Contents**

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 also requires a minimum sales commitment over a period of time, which if not met, would result in the technology being 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 due to the limitations on our resources and the many risks of conducting clinical trials, as described above 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.

Further, in February 2006, we entered into a Sublicensing and Distribution Agreement with Pfizer, S.A. de C.V. 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 ingredients for FACTIVE required by Pfizer Mexico in Mexico. In August 2006, we entered into a Supply, Development and Marketing Agreement with Abbott Laboratories Canadian affiliate. Under this agreement, we are obligated to exclusively supply all finished packaged FACTIVE product required by Abbott in Canada. 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 to that we will be able to remain in compliance with such responsibilities.

**ANTARA**

Our exclusive rights to ANTARA are licensed to us by Ethypharm, S.A. 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 certain minimum annual sales of ANTARA until February 2012 or make payments to Ethypharm to compensate for the difference. 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.

**We will depend on key personnel in a highly competitive market for skilled personnel.**

We will be highly dependent on the principal members of our senior management and key scientific 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; Philippe M. Maitre, Senior Vice President and Chief Financial Officer; and Dominick Colangelo, Esq., Executive Vice President, Corporate Development and Operations. The term of each employment agreement continues until it is terminated by the officer or Oscient.

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.

**Changes in the expensing of stock-based compensation will 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 heavily 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



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## **Table of Contents**

record expense for the fair value of stock options 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 effects on earnings, it may be difficult for us to attract and retain qualified scientific, technical and business personnel.

### **Sales of FACTIVE in European countries in which we do not have rights to market the product could adversely affect sales in the European countries in which we have exclusive rights to market the product.**

Our exclusive rights to market FACTIVE in Europe are limited to 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 and Vatican City. These countries included all of the members of the European Union on the date of the original agreement to license FACTIVE. However, in 2004, a number of additional European countries in which we do not have rights to market FACTIVE were admitted as members of the European Union. If LG Life Sciences were to sell FACTIVE or license a third party to sell FACTIVE in such countries, our ability to maintain our projected profit margins based on sales in the territories covered by the LG Life Sciences license agreement may be adversely affected because customers in our territory may purchase FACTIVE from neighboring countries in the European Union and our ability to prohibit such purchases may be limited under European Union antitrust restrictions.

### **Failure to secure distribution partners or obtain regulatory approval in foreign jurisdictions will prevent us from marketing FACTIVE abroad.**

We have entered into commercialization relationships with Pfizer, S.A. de C.V. (Pfizer Mexico) and Abbott Laboratories, Ltd. (Abbott Canada) whereby we sublicensed our rights to sell FACTIVE tablets in Mexico to Pfizer Mexico and in Canada to Abbott Canada, respectively. We intend to further market FACTIVE through distribution partners in the Europe Union. We may not be able to secure distribution partners at all, or those that we do secure, including our relationships with Pfizer Mexico and Abbott Canada, may not be successful in obtaining regulatory approval or in marketing and distributing FACTIVE. If we are not able to secure distribution partners or those partners are unsuccessful in their efforts, it would significantly limit the revenues that we expect to obtain from the sales of FACTIVE.

Further, in order to market FACTIVE in the European Union, we or our distribution partners must obtain separate regulatory approvals. Obtaining foreign approvals may require additional trials and expense. For instance, our predecessor's original regulatory filing in the UK 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.

### **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 September 30, 2006, we had approximately \$239,000,000 of indebtedness outstanding (including accrued interest and excluding trade payables, accrued liabilities and accrued facilities impairment charges), which includes \$40 million in revenue interest that entitles Paul Capital to receive a royalty on the sales of both ANTARA and FACTIVE. Approximately \$23 million of outstanding indebtedness will mature in 2009, approximately \$20 million of outstanding indebtedness will mature in 2010 and approximately \$153 million of indebtedness will mature in 2011. 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 while arriving at maturity;

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;

reduce funds available for use in our operations;

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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 due to provisions in the Revenue Interest 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 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 to due to any of the factors described in this report or for other reasons, 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 could have a material adverse effect on our business, operating results and financial condition.

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## **Table of Contents**

Our ability to meet our debt service obligations will depend upon our future performance, which will be subject to financial, business and other factors affecting our operations, many of which are beyond our control.

### **RISKS RELATED TO OUR INDUSTRY**

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

Our ability to commercialize FACTIVE tablets, ANTARA capsules, 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 offering a variety of benefit packages. 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.

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 FACTIVE tablets, ANTARA capsules, 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 FACTIVE and ANTARA 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 million per occurrence and \$10 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.

**Table of Contents**

**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 in this section of the report, as well as other factors, including:

our ability to successfully commercialize FACTIVE tablets and ANTARA capsules;

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

the results of our clinical trials for Ramoplanin and additional indications for FACTIVE and the pace of our progress in those clinical trials;

whether we will be able to successfully integrate ANTARA into our sales and marketing efforts;

our ability to license or develop other compounds for clinical development;

the timing of the achievement of our 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 biopharmaceutical industry generally;

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

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

comments by securities analysts, or our failure to meet market expectations.

Over the two-year period ending September 30, 2006 the closing price of our common stock as reported on the Nasdaq National Market ranged from a high of \$3.80 to a low of \$0.60. 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.

**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 FACTIVE tablets and ANTARA capsules;

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

the progress of our clinical trials for FACTIVE, Ramoplanin and our other product candidates;

our success in concluding deals to acquire additional approved products and product candidates;

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.

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

Please see our Current Report on Form 8-K as filed with the Securities and Exchange Commission on August 21, 2006 and incorporated herein by reference.

**ITEM 3: DEFAULTS UPON SENIOR SECURITIES**

None

**Table of Contents**

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

The Board of Directors has called a Special Meeting of Shareholders of Oscient Pharmaceuticals Corporation to be held on November 14, 2006 at 10:00 a.m., local time, at the offices of Ropes & Gray LLP, One International Place, 36th floor, Boston, Massachusetts. At the Special Meeting, shareholders will be asked to vote on a proposal to approve an amendment to Oscient's Amended and Restated Articles of Organization, as amended to date, to effect a reverse stock split of the issued and outstanding shares of Oscient's common stock (such split to combine eight (8) shares of our outstanding Common Stock into one (1) share of our Common Stock), which may be filed at the discretion of our Board of Directors at any time prior to the Company's next annual meeting of shareholders without further approval or authorization of the Company's shareholders. Following the implementation of such amendment, the par value and the number of authorized shares of our Common Stock will remain unchanged. This proposal is presented in full in a proxy statement filed with the Securities and Exchange Commission on October 10, 2006.

**ITEM 5: OTHER INFORMATION**

None.

**ITEM 6: EXHIBITS**

**Description**

- 10.1 Supply, Distribution and Marketing Agreement dated as of August 9, 2006 by and among Oscient Pharmaceuticals Corporation, Abbott International, LLC, Abbott Laboratories, Ltd. and Abbott Laboratories\*
- 10.2 Revenue Interest Assignment Agreement dated as of July 21, 2006 and restated on August 18, 2006 by and among Oscient Pharmaceuticals Corporation, Guardian II Acquisition Corporation and Paul Royalty Fund Holding II \*
- 10.3 Note Purchase Agreement dated as of July 21, 2006 by and between Guardian II Acquisition Corporation and Paul Royalty Fund Holding II
- 10.4 Common Stock and Warrant Purchase Agreement dated as of July 21, 2006 by and between Oscient Pharmaceuticals Corporation and Paul Royalty Fund Holding II
- 10.5 Letter Agreement August 31, 2006 by and between Oscient Pharmaceuticals Corporation and Gary Patou, M.D.
- 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.
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\* Confidential information has been omitted from this exhibit and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request.



**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**

**Senior Vice President & Chief Financial Officer**

**(Principal Financial Officer)**

November 9, 2006

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**OSCIENT PHARMACEUTICALS CORPORATION**

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