

OSCIENT PHARMACEUTICALS CORP

Form 10-Q

May 10, 2006

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**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

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**FORM 10-Q**

**x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES AND EXCHANGE ACT OF 1934**  
For the Quarterly Period Ended: March 31, 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)

**MASSACHUSETTS**  
(State or other jurisdiction of

incorporation or organization)

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

Identification no.)

**1000 WINTER STREET, SUITE 2200**

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

**02451**  
(Zip code)

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

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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

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):

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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  
\$0.10 PAR VALUE**

**96,087,929 Shares  
Outstanding May 5, 2006**

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

	March 31, 2006 (Unaudited)	December 31, 2005
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 52,350	\$ 65,618
Marketable securities (held-to-maturity)		2,696
Restricted cash	5,346	5,386
Interest receivable	336	461
Notes receivable	561	561
Accounts receivable	8,987	6,206
Inventories	12,909	14,187
Prepaid expenses and other current assets	3,563	4,340
Total current assets	84,052	99,455
Property and Equipment, at cost:		
Manufacturing and computer equipment	4,613	4,622
Equipment and furniture	1,160	1,160
Leasehold improvements	135	135
	5,908	5,917
Less Accumulated depreciation	4,248	4,069
	1,660	1,848
Restricted cash	6,454	6,344
Long-term notes receivable	1,599	1,739
Other assets	4,424	4,573
Intangible assets, net	64,416	65,607
Goodwill	61,529	61,529
	\$ 224,134	\$ 241,095
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 5,490	\$ 6,447
Accrued expenses and other current liabilities	12,795	10,163
Current portion of accrued facilities impairment charge	2,604	2,175
Accrued restructuring charge	965	1,076
Clinical trial expense accrual	1,552	1,844
Deferred revenue	233	
Total current liabilities	23,639	21,705
Long-term liabilities:		
Long-term obligations, net of current maturities	175,060	175,060

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Noncurrent portion of accrued facilities impairment charge	13,188	14,029
Other long-term liabilities	2,504	2,200
Noncurrent portion of deferred revenue	78	
Commitments		
Shareholders' Equity:		
Common stock, \$0.10 par value - Authorized - 174,375 shares, Issued and Outstanding - 78,083 and 77,350 in 2006 and 2005, respectively	7,808	7,735
Series B restricted common stock, \$0.10 par value - Authorized - 625 shares, Issued and Outstanding - None in 2006 and 2005		
Additional paid-in-capital	359,552	357,968
Accumulated deficit	(357,532)	(337,428)
Deferred compensation		(11)
Note receivable from officer	(163)	(163)
Total shareholders' equity	9,665	28,101
	\$ 224,134	\$ 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 March 31, 2006	March 31, 2005
Revenues:		
Product sales	9,246	3,912
Co-promotion	1,545	
Biopharmaceutical/other	182	34
<b>Total revenues</b>	<b>10,973</b>	<b>3,946</b>
Costs and expenses(1):		
Cost of product sales	2,750	2,066
Research and development	2,928	6,004
Selling and marketing	20,445	20,108
General and administrative	3,640	5,029
<b>Total costs and expenses</b>	<b>29,763</b>	<b>33,207</b>
Loss from operations	(18,790)	(29,261)
Other income (expense):		
Interest income	696	870
Interest expense	(2,010)	(2,044)
Gain on sale of fixed assets		38
Income from sale of intellectual property		2,500
Other income		40
<b>Net other income (expense)</b>	<b>(1,314)</b>	<b>1,404</b>
Loss from continuing operations	(20,104)	(27,857)
Income from discontinued operations		21
<b>Net loss</b>	<b>(20,104)</b>	<b>(27,836)</b>
Loss from continuing operations per common share:		
Basic and diluted	(0.26)	(0.37)
Loss from discontinued operations per common share:		
Basic and diluted		
<b>Net loss per common share:</b>		
Basic and diluted	(0.26)	(0.37)
Weighted average common shares outstanding:		
Basic and diluted	77,618	75,906
(1) Includes non-cash stock-based compensation as follows:		
Cost of product sales	12	
Research and development	50	836
Selling and marketing	393	

General and administrative	643	112
	1,098	948

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

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(in thousands)

	Three Months Ended March 31, 2006	March 31, 2005
<b>Cash Flows from Operating Activities:</b>		
Loss from continuing operations	\$ (20,104)	\$ (27,857)
Adjustments to reconcile loss from continuing operations to net cash used in operating activities:		
Depreciation and amortization	1,379	1,330
Provision for excess and obsolete inventories	23	
Non-cash interest expense	366	406
Gain on disposal of fixed assets		(38)
Stock-based compensation	1,098	948
Changes in assets and liabilities		
Interest receivable	125	642
Accounts receivable	(2,781)	(787)
Inventories	1,255	(2,981)
Prepaid expenses and other current assets	777	(2,485)
Accounts payable	(957)	(1,568)
Accrued expenses and other current liabilities	2,632	1,514
Clinical trial expense accrual	(292)	1,756
Deferred revenue	311	(389)
Accrued facilities impairment charge	(573)	(703)
Accrued restructuring charge	(111)	(511)
Other long-term liabilities	304	307
Net cash used in operating activities	(16,548)	(30,416)
<b>Cash Flows from Investing Activities:</b>		
Proceeds from maturities of marketable securities	2,696	46,665
Purchases of property and equipment		(339)
Proceeds from sale of property and equipment		135
Increase in restricted cash	(70)	(32)
(Increase) decrease in other assets	(56)	14
Proceeds from notes receivable	140	
Issuance of notes receivable		(1,387)
Net cash provided by investing activities	2,710	45,056
<b>Cash Flows from Financing Activities:</b>		
Proceeds from exercise of stock options	122	353
Proceeds from issuance of stock under the employee stock purchase plan	448	200
Payments on current maturities of long-term obligations		(292)
Net cash provided by financing activities	570	261
<b>Cash Flows from Discontinued Operations (Revised):</b>		
Operating cash flows		21
Total		21



<b>Net (Decrease) Increase in Cash and Cash Equivalents</b>	(13,268)	14,922
<b>Cash and Cash Equivalents, beginning of period</b>	65,618	64,743
<b>Cash and Cash Equivalents, end of period</b>	\$ 52,350	\$ 79,665

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

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**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 biopharmaceutical company committed to the clinical development and commercialization of important new therapeutics to serve unmet medical needs. On February 6, 2004, the Company completed a merger with GeneSoft Pharmaceuticals, Inc. (Genesoft), a privately-held pharmaceutical company based in South San Francisco, California, whereby Genesoft became the Company's wholly owned subsidiary. The Company's lead product is the fluoroquinolone antibiotic FACTIVE® (gemifloxacin mesylate) tablets, indicated for the treatment of community-acquired pneumonia (CAP) of mild to moderate severity and acute bacterial exacerbations of chronic bronchitis (AECB). The Company launched FACTIVE tablets in September 2004. In May 2005, the Company began co-promoting in the United States Auxilium Pharmaceuticals Inc.'s (Auxilium) product, TESTIM gel, a topical 1% testosterone gel indicated for the treatment of male hypogonadism.

The Company has two product candidates currently in development for the hospital marketplace in the United States, including a novel antibiotic candidate, Ramoplanin, which is currently in clinical development for the treatment of *Clostridium difficile*-associated disease (CDAD), a serious hospital-acquired infection. Ramoplanin has completed Phase II clinical development, and the Company recently agreed with the FDA on a Special Protocol Assessment for its continued clinical development and is advancing the clinical program of Ramoplanin toward a Phase III trial. The Company's other product candidate is an intravenous formulation of FACTIVE that is being studied for formulation development.

The Company's preclinical development programs include an oral peptide deformylase (PDF) inhibitor series for the potential treatment of respiratory tract infections. The Company also has several pharmaceutical alliances focused on the development of novel therapeutics and diagnostics for chronic human diseases and certain infectious diseases. These alliances were formed in previous years based on the Company's genomics drug discovery expertise. The Company's business strategy has shifted away from gene discovery and partnerships of this type to focus on the development and commercialization of pharmaceutical products.

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, which began shipping in the third quarter of 2004. In the second quarter of 2005, the Company began recognizing co-promotion revenue of TESTIM gel in connection with its agreement with Auxilium. Other historical sources of revenue include biopharmaceutical alliances and royalties from the divested genomic services business. In future periods, the Company expects that its revenues derived from biopharmaceutical alliances will continue to decrease, while product revenues and co-promotion revenues are expected to increase based on the anticipated increased volume of prescriptions of FACTIVE tablets and TESTIM testosterone gel.



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The Company expects 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 severity of the annual respiratory tract infection season may cause the Company's product sales to vary from year to year. Due to these seasonal fluctuations in demand, 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 No. 104, Revenue Recognition (a replacement of SAB 101) (SAB No. 104) and recognizes revenue from FACTIVE product sales upon delivery of product to wholesalers, when persuasive evidence of an arrangement exists, the fee is fixed or determinable, title to product and associated risk of loss has passed to the wholesaler and collectability of the related receivable is reasonably assured. All revenues from product sales are recorded net of applicable allowances for sales returns, rebates, special promotional programs, and discounts. For arrangements where the risk of loss has not passed to wholesalers or pharmacies, the Company defers the recognition of revenue by recording deferred revenue until such time that risk of loss has passed. Also, the cost of FACTIVE 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 the Company's co-promotion agreement with Auxilium from the sale of TESTIM gel, a product developed by Auxilium, is 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 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. 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.

### *Biopharmaceutical/Other Revenue*

Prior to the merger with Genesoft in 2004, the Company pursued biopharmaceutical revenues through alliance partnerships with pharmaceutical companies and through government grants. 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.

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.

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 No. 00-21, Revenue Arrangements with Multiple Deliverables (EITF No. 00-21). In accordance with EITF No. 00-21, the up-front payment related to a license agreement is recognized as revenue over the term of the Company's obligations under the agreement.

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

The Company's FACTIVE product sales 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 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



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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 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. The Company's product has a 36-month expiration period from the date of manufacturing into a tablet. At March 31, 2006 and December 31, 2005, the Company's product return reserve was approximately \$824,000 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.

### *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 March 31, 2006 and December 31, 2005, the balance of the cash discounts reserve was approximately \$140,000 and \$50,000, respectively.

### *Rebates*

The liability for managed care rebates is calculated upon historical and current rebate redemption and utilization rates contractually submitted by each state. As of March 31, 2006 and December 31, 2005, the balance of the accrual for managed care rebates was approximately \$420,000 and \$381,000, respectively. Considering the estimates made by the Company, as well as estimates prepared by third party utilization reports that are necessary in evaluating the required liability balance, the Company believes its estimates are reasonable, and changes, if any, from those estimates would not be material to the financial statements. As of March 31, 2006, there have been no material changes to the Company's estimates in the periods presented.

### *Special Promotional Programs*

The Company has offered certain promotional incentives to date to its customers 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 Rebate Program*

During the first quarter of 2006, the Company initiated a sample card program 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 this program in accordance with EITF No. 01-09, Accounting for Consideration Given by a Vendor to a Customer (EITF No. 01-09). 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. The program expired on March 31, 2006, at which point the balance of the liability for this sample card program was approximately \$2,606,000.

#### *Voucher Rebate Program*

During the fourth quarter of 2005, the Company initiated a voucher rebate program whereby it offered mail-in rebates 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 based upon the historical rebate redemption rates for the similar completed program that the Company commenced in the first quarter of 2005. As of March 31, 2006 and December 31, 2005, the balance of the liability for this voucher program was approximately \$23,000 and \$93,000, respectively. The program will expire on April 30, 2006 and the liability will be adjusted for the actual redemption rate.

### **(c) Clinical Trial Expense Accrual**

The Company's clinical development trials related to FACTIVE and Ramoplanin 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 three months ended March 31, 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 outside parties.



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As a condition to the approval to sell FACTIVE tablets, the FDA has required, as a post-marketing study commitment, that the Company 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 will include patients of different ethnicities to gain safety information in populations not substantially represented in the existing clinical trial program. This Phase IV trial, with approval from the FDA, 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 related to this study, the Company currently estimates that between \$7-8 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 October 2005, the Company submitted a supplemental New Drug Application to the FDA for approval to promote the five-day treatment of FACTIVE tablets for this indication. In January 2006, the FDA accepted the submission of filing.

**(d) Accounts Receivable**

Trade accounts receivable consists of amounts due from wholesalers for the purchase of FACTIVE. Ongoing evaluations of customers are performed and collateral is generally not required. As of March 31, 2006 and December 31, 2005, the Company has not reserved any amount for bad debts related to the sale of FACTIVE. The Company continuously reviews all customer accounts to determine if an allowance for uncollectible accounts is necessary. The Company currently provides substantially all of its distributors with payment terms of up to 30 days on purchases of FACTIVE. Amounts past due from customers are determined based on contractual payment terms. Through March 31, 2006, payments have generally been made in a timely manner.

The following table represents accounts receivable (in thousands):

	As of	As of
	March 31, 2006	December 31, 2005
Trade, net	\$ 7,251	\$ 3,170
Co-promotion	1,589	1,825
Other	147	1,211
Total	\$ 8,987	\$ 6,206

**(e) Restricted Cash**

The Company's restricted cash primarily consists of amounts required to be paid for the first six semi-annual interest payments due in connection with the convertible debt offering completed in May 2004. As of March 31, 2006, the remaining three semi-annual interest payments, totaling approximately \$8,019,000, which are payable on April 15<sup>th</sup> and October 15<sup>th</sup> of 2006 and April 15<sup>th</sup> of 2007 are restricted. At March 31, 2006, the restricted cash balance is approximately \$7,670,000 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 (which is lower than the useful life of the assets).



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

Depreciation expense was approximately \$188,000 and \$138,000 for the three-month periods ended March 31, 2006 and 2005, respectively.

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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. Inventories consist of FACTIVE raw material in powder form and work-in-process of approximately \$9,770,000 and \$9,770,000, and FACTIVE finished tablets of approximately \$3,139,000 and \$4,417,000, as of March 31, 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 March 31, 2006 and December 31, 2005, there was approximately \$1,079,000 and \$2,072,000, respectively, in FACTIVE sample product to be used for FACTIVE marketing programs, which is classified as an other current asset in the accompanying consolidated balance sheet.

The following table represents trade inventories (in thousands):

	As of	As of
	March 31, 2006	December 31, 2005
Raw material	\$ 8,418	\$ 8,418
Work-in-process	1,352	1,352
Finished goods	3,139	4,417
Total	\$ 12,909	\$ 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 securities, 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 39,151 and 38,365 shares of the Company's common stock (prior to the application of the treasury stock method) during the three month periods ended March 31, 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.

*TESTIM*

Pursuant to the Company's co-promotion arrangement with Auxilium, Auxilium is responsible for the manufacture and distribution of TESTIM. Auxilium relies on a single third party source for the manufacture of TESTIM as well as certain raw materials used to produce TESTIM. The disruption or termination of the supply of TESTIM by Auxilium or its third party contractors could have a material adverse effect on the Company's business, financial position and results of operations.

**(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

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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.

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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
		Three months ended March 31, 2006	2
Three months ended March 31, 2005	2	15%	68%

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
		As of March 31, 2006	2
As of December 31, 2005	2	27%	54%

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

**(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 Income (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 income (loss) on an annual and interim basis. Comprehensive income (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 three month periods ended March 31, 2006 and 2005, the net loss is equal to the comprehensive loss.

**(m) Reclassifications**

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.

**(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

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No. 131, are the chief executive officer and chief financial officer. Prior to sale of the genomics services segment in 2003, the Company had viewed its operations and managed its business as principally two operating segments: genomics services and biopharmaceutical. In 2004, the Company exited the genomics services segment, merged with Genesoft and launched FACTIVE on September 9, 2004 and began its co-promotion of TESTIM in May 2005. As a result, the Company believes it now operates in one segment called biopharmaceutical and product sales and the financial information disclosed herein represents all of the material financial information related to the Company's one operating segment. In addition, in the fourth quarter of 2004, the Company reclassified all periods to present the revenues and expenses associated with the genomics business as discontinued operations as the Company no longer had significant involvement in the cash flows of this business.

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All of the Company's product revenues are generated in the United States and all assets are located in the United States. All 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 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 March 31, 2006, the Company does not believe that any of its long-lived assets, goodwill, or other intangible assets are impaired.

### **(p) Recent Accounting Pronouncements**

#### *Accounting for Inventory Costs*

On November 24, 2004, the FASB issued SFAS No. 151, *Inventory Costs*, an amendment of ARB No. 43, Chapter 4 (SFAS No. 151). The amendments made by SFAS No. 151 clarify that abnormal amounts of idle facility expense, freight, handling costs, and wasted materials (spoilage) should be recognized as current-period charges and require the allocation of fixed production overheads to inventory based on the normal capacity of the production facilities. SFAS No. 151 is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. Earlier application is permitted for inventory costs incurred during fiscal year beginning after November 24, 2004. The Company applied the provisions of SFAS No. 151 starting January 1, 2006 on a prospective basis as required by SFAS 151. The application of SFAS No. 151 did not have a material effect on the Company's financial condition or results of operations.

#### *Accounting Changes and Error Corrections*

In May 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections* a replacement of APB Opinion No. 20 and FASB Statement No. 3 (SFAS No. 154). SFAS No. 154 changes the requirements for the accounting for and reporting of a change in accounting principle. SFAS No. 154 applies to all voluntary changes in accounting principle. It also applies to changes required by an accounting pronouncement in the unusual instance that the pronouncement does not include specific transition provisions. When a pronouncement includes specific transition provisions, those provisions should be followed. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. Early adoption is permitted for accounting changes and corrections of errors made in fiscal years after the date the statement was issued. The Company applied the provisions of SFAS No. 154 starting January 1, 2006 on a prospective basis. The application of SFAS No. 154 did not have a material effect on the Company's financial condition or results of operations.

### **(3) 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



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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 three month period ended March 31, 2006 (in thousands):

	<b>Balance at</b>		<b>Balance at</b>
	<b>December 31,</b>	<b>Cash</b>	<b>March 31,</b>
	<b>2005</b>	<b>Payments</b>	<b>2006</b>
Restructuring facility lease liability	\$ 1,076	\$ (111)	\$ 965

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 three month period ended March 31, 2006 (in thousands):

	<b>Balance at</b>			<b>Balance at</b>
	<b>December 31,</b>	<b>Cash</b>	<b>Interest</b>	<b>March 31,</b>
	<b>2005</b>	<b>Payments</b>	<b>Accretion</b>	<b>2006</b>
Assumed facility lease liability	\$ 16,204	\$ (573)	\$ 161	\$ 15,792

**(4) Stock-Based Compensation**

Effective January 1, 2006, the Company adopted SFAS No. 123(R), Share-Based Payment, (SFAS No. 123R) using the modified prospective 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 three months ended March 31, 2006 includes (1) compensation cost for all share-based payments granted prior to, but not vested as of December 31, 2005, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, Accounting for Stock-Based Compensation, 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. Results for prior periods have not been 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 March 31, 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 over a two to four year time period and options granted to non-employees vest 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 life 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 options and restricted stock awards provide for accelerated vesting if there is a change in control. As of March 31, 2006, 10,366,100 shares were



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authorized and 733,835 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.

**Table of Contents***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 current offering period began January 1, 2006 and is scheduled to end 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 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. Upon adoption of SFAS 123R, the Company began recording stock-based compensation expense related to the ESPP. As of March 31, 2006, 1,500,000 shares were authorized and 415,332 shares were available for future issuance under this plan.

Prior to January 1, 2006, the Company applied the intrinsic value method under 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</b>
	<b>Months Ended</b>
	<b>March 31, 2005</b>
Net loss as reported	\$ (27,836)
Add: Share-based employee compensation cost, included in the determination of net loss as reported	948
Less: Total share-based compensation expense determined under the fair value method for all employee awards	(1,714)
Pro forma net loss	\$ (28,602)
Basic and diluted net loss per share	
As reported	\$ (0.37)
Pro forma	\$ (0.38)

The adoption of SFAS No. 123R increased the Company's first quarter 2006 operating loss, net loss, and cash flows used in operating activities by \$1,051,000 and basic and diluted net loss per share by \$0.01. 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 Company's adoption of SFAS No. 123R did not affect operating loss, loss before income tax benefit, net loss, cash flow from operations, cash flow from financing activities or basic and diluted net loss per share during the three months ended March 31, 2005.

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:

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	Three Months Ended March 31,	
	2006	2005
Expected volatility	52.75-53.41 %	49.14-47.79%
Risk-free interest rate	4.35-4.72%	3.71-4.17%
Expected life (years)	5-6.25	5
Expected dividend		

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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. For option grants made subsequent to the adoption of SFAS 123R, the expected life of stock options granted is based on the simplified method allowable under SAB 107, "Share-Based Payment". Accordingly, the expected term is presumed to be the midpoint between the vesting date and the end of the contractual term. 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 for post-vesting terminations is necessary. 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 March 31, 2006, and changes during the three month period then ended is presented below (in thousands, except weighted average data):

	Number of Options	Weighted- average Exercise Price	Weighted-average	
			Remaining Contracted Term in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2005	8,861	\$ 4.06		
Granted	1,183	\$ 1.95		
Exercised	(83)	\$ 1.51		
Forfeited/Cancelled	(753)	\$ 5.73		
Outstanding at March 31, 2006	9,208	\$ 3.68	8.06	\$ 2,305
Exercisable at March 31, 2006	4,415	\$ 4.47	6.99	\$ 1,992

The total compensation cost that has been charged to income during the first quarter of 2006 was approximately \$1,051,000. 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 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 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 has applied an annual forfeiture rate of 16.85% to options in calculating total recognized compensation cost as of March 31, 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 three months ended March 31, 2006 and 2005 were \$1.06 and \$1.44, respectively. For the three months ended March 31, 2006, the Company granted 1,183,000 in stock options with a weighted average exercise price of \$1.95. For the three months ended March 31, 2005, the Company granted 2,251,995 in stock options with a weighted average exercise price of \$3.02.

During the three months ended March 31, 2006 and 2005, the total intrinsic value of options exercised was \$68,000 and \$1,593,000, respectively. The total amount of cash received from exercise of these options during the three months ended March 31, 2006 and 2005 was \$122,000 and \$353,000 respectively.

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The Option Plans also provide 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 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 March 31, 2006, is indicated in the following table (in thousands, except weighted average data):

	Number of Shares	Weighted-average grant date fair value
Outstanding at December 31, 2005		\$
Granted	420	1.93
Vested		
Forfeited	(2)	1.93
Outstanding at March 31, 2006	418	\$ 1.93

As of March 31, 2006, there was \$8.0 million of total unrecognized compensation cost related to unvested share based awards. This cost is expected to be recognized over a weighted average period of 2.1 years. The Company expects approximately 4,333,000 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.

**(5) 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 March 31, 2006 and 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 March 31, 2006 and December 31, 2005, cash and cash equivalents consisted of money market funds and commercial paper and marketable securities consisted of corporate obligations. At March 31, 2006 and December 31, 2005, the average maturity of the Company's investments was approximately 0.5 months 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.

At March 31, 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>March 31, 2006</b>				
Cash and Cash Equivalents:				
Cash	\$ 43,869	\$	\$	\$ 43,869
Money market funds	7,731			7,731
Short-term corporate obligations	750			750
Total cash and cash equivalents	\$ 52,350	\$	\$	\$ 52,350
<b>December 31, 2005</b>				
Cash and Cash Equivalents:				
Cash	\$ 43,069	\$	\$	\$ 43,069
Money market funds	11,326			11,326

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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

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**(6) 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 \$2,740,000 related to the repayment of security deposits made by the Company. The notes bear interest at rates ranging from 5.5% to 6.25% and have expiration dates ranging from March 2008 to August 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.

**(7) Long-Term Obligations**

In the quarter ended June 26, 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 March 31, 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.

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.

**(8) Supply Agreement**

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

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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 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.

Gross margins of FACTIVE, after standard product costs and royalties but excluding amortization of intangible assets, continue to be in the 70%-75% range through September 2006 and are expected to be in the 65%-70% range thereafter. However, as a result of the amendment to the LG agreement discussed above, gross margins may be in the 70%-75% range after September 2006 if significantly higher sales of FACTIVE are achieved, which would require a significant expansion of the sales effort.

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

On April 11, 2005, the Company entered into a co-promotion agreement (the Co-Promotion Agreement) with Auxilium under which the Company and Auxilium have begun to co-promote in the U.S. Auxilium's marketed product, TESTIM, a topical 1% testosterone gel indicated for the treatment of male hypogonadism. Pursuant to the Co-Promotion Agreement, the Company has the exclusive right to promote TESTIM jointly with Auxilium to primary care physicians. The initial term of the Co-Promotion Agreement with Auxilium ends on April 30, 2007. The Company may extend the agreement for two consecutive two-year periods provided that it has met certain milestones for each extension related to physician detailing, market share and gross sales. If these milestones are met and the Company does not elect to terminate the Co-Promotion Agreement, the first extension period will end on December 31, 2008 and the second extension period will end on April 30, 2011.

Both organizations have established and continue to jointly develop a promotion plan which sets forth the responsibilities of both parties with respect to the marketing and promotion of TESTIM in the U.S. for the primary care physician market. The Company is obligated to share TESTIM promotional expenses to this physician market equally with Auxilium. The Company and Auxilium share equally expenses related to the promotion of TESTIM to the primary care physician market. Each party will be responsible for the costs associated with its own sales force. In addition, 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 cumulative specified sales threshold. These fees are classified as co-promotion revenue in the accompanying statements of operations. The specific percentage is based upon TESTIM sales levels attributable to primary care physicians and the marketing expenses incurred by the Company in connection with the promotion of TESTIM under the Co-Promotion Agreement. There is no cost of goods sold associated with co-promotion revenue, and the selling and marketing expenses related to co-promotional sales are classified as selling and marketing expenses in the accompanying statement of operations. The Co-Promotion Agreement can be terminated by either party upon the occurrence of certain termination events, including if a generic form of TESTIM is approved and sold in the United States, in which case Auxilium is obligated to pay the Company a specified percentage of the profits for product sales for the following two years. Also, the Company has been granted the exclusive option to co-promote any future Auxilium product candidate that treats male hypogonadism and contains testosterone as the active ingredient.





**Table of Contents****(10) Sublicense Agreement**

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 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 ingredient 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.

**(11) Subsequent Events**

On April 11, 2006, the Company closed a private placement of its common stock with institutional and other accredited investors pursuant to which the Company sold an aggregate of 18,035,216 shares of its common stock at a price of \$1.93 per share and warrants to purchase 9,017,608 shares of common stock at a price of \$0.125 per share of the common stock issuable pursuant to such warrants. The warrants have an exercise price of \$2.22 per share and a term of five years.

**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 TESTIM®, our discount and rebate programs for FACTIVE, gross margin in future periods, our ability to obtain approval from the FDA for a five-day course of therapy for CAP, our discussions with the FDA regarding our ABS filing and the FDA's convening of an Advisory Committee related to the ABS sNDA, 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 our 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 committed to the clinical development and commercialization of new therapeutics to serve unmet medical needs. We currently promote two products in the U.S. pharmaceutical market. Our lead product is the fluoroquinolone antibiotic FACTIVE® (gemifloxacin mesylate) tablets, indicated for the treatment of community-acquired pneumonia of mild to moderate severity (CAP) and acute bacterial exacerbations of chronic bronchitis (AECB). The commercial sale of FACTIVE began in September 2004 and FACTIVE is currently promoted nationally by a sales team comprised of approximately 280 representatives. We also co-promote Auxilium Pharmaceuticals, Inc.'s marketed product, TESTIM gel, a topical 1% testosterone gel indicated for the treatment of male hypogonadism. Additionally, we are developing a novel antibiotic candidate, Ramoplanin, for the treatment of *Clostridium difficile*-associated disease.

We have incurred significant operating losses since our inception. As of March 31, 2006, we had an accumulated deficit of approximately \$357.5 million. We expect to incur additional operating losses over the next several years due to



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the implementation of manufacturing, distribution, marketing and sales capabilities, as well as continued research and development efforts and clinical trials.

### **FACTIVE**

#### *Overview*

Our lead product is FACTIVE tablets, 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.

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.

Gross margins of FACTIVE sales in the U.S., after standard product costs and royalties but excluding amortization of intangible assets, continue to be in the 70%-75% range through September 2006 and are expected to be in the 65%-70% percent range thereafter. As a result of the March 2005 amendment to the LG agreement discussed above, gross margins may be in the 70%-75% range after September 2006 if significantly higher sales of FACTIVE are achieved, which would require a significant expansion of the sales effort.

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 will include patients

of different ethnicities to gain safety information in populations

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not substantially represented in the existing clinical trial program. Patient enrollment for this Phase IV trial, with approval from the FDA, commenced during the fall of 2004 and is scheduled to be completed within three to four years of commencement. Although we cannot predict with certainty the remaining costs related to this study, we currently estimate it will cost between \$7-8 million of additional spending to complete the study.

### *Commercialization and Development*

We began selling FACTIVE tablets in September 2004 with an initial sales force of 100 representatives and, as of March 2006, continue to utilize a full-time sales force of approximately 250 sales representatives, to be supplemented by approximately 30 part-time sales personnel anticipated to begin work in June 2006.

We are also seeking to expand the commercial opportunities for FACTIVE through additional development and clinical study plans for the product. 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. The FDA is reviewing our sNDA seeking marketing approval for the use of FACTIVE for the five-day treatment of CAP. The FDA granted a standard ten-month review period for the five-day CAP sNDA and is expected to act on the filing by the end of September 2006. The acceptance for filing of the CAP sNDA does not assure approval.

As part of the FACTIVE development program, several studies relating to acute bacterial sinusitis, or ABS, were completed; and, in November 2005, we filed an sNDA for ABS. In January 2006, the FDA informed us that it had refused to accept for filing the sNDA for the five-day treatment of ABS. In its refusal to accept the sNDA filing for ABS, the FDA indicated that FACTIVE did not exhibit an acceptable risk versus benefit profile for the ABS indication. In addition, the FDA expressed the opinion that demonstrating an acceptable risk versus benefit profile for FACTIVE in ABS was not feasible, given the FDA's view of the potential risk of rash in those patients. As part of the process to address the FDA's concerns related to this indication, we met with officials at the FDA to continue the dialogue regarding appropriate subsequent actions. Through these discussions, we requested that the FDA file the sNDA over protest. The FDA has now filed the sNDA over protest and we expect a response from the FDA on the ABS sNDA by the end of 2006. More recently, we received notification from the FDA that it intends to convene an Advisory Committee to review the sNDA for ABS which could take place this fall. Given the FDA's original decision to refuse to accept the sNDA for the treatment of ABS, we cannot guarantee that the ABS indication will ever be approved by the FDA.

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 fee, milestone payments upon obtaining certain regulatory approvals and sales goals as well as royalties on future sales. These royalty rates are subject to reduction upon expiration of certain patents in Mexico for FACTIVE or if a generic form of gemifloxacin has a material impact on Pfizer Mexico's sales volumes in Mexico. Pfizer Mexico is obligated to exclusively purchase from us, and we must exclusively supply, all active pharmaceutical ingredient 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 us or our designee.

### **Co-Promotion of TESTIM**

On April 11, 2005, we entered into a co-promotion agreement with Auxilium Pharmaceuticals, Inc. under which we and Auxilium will co-promote in the United States Auxilium's marketed product, TESTIM gel, a topical 1% testosterone gel indicated for the treatment of male hypogonadism. Pursuant to the agreement, we have the exclusive right to promote TESTIM gel jointly with Auxilium to primary care physicians. The initial term of the agreement ends on April 30, 2007. We may extend the agreement for two consecutive two-year periods provided that we have met certain milestones for each extension related to physician detailing, market share and gross sales. If these milestones are met and we do not elect to terminate the co-promotion agreement, the first extension period will end on December 31, 2008 and the second extension period will end on April 30, 2011.

Both organizations have established and continue to develop a promotion plan which sets forth the responsibilities of both parties with respect to the marketing and promotion of TESTIM gel in the U.S. primary care physician market. We are obligated to share TESTIM promotional expenses to this physician market equally with Auxilium. Each party will be responsible for the costs associated with its own sales force. In addition, 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 sales threshold. 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 gel under the co-promotion agreement. The co-promotion agreement can be terminated by either party upon the occurrence of certain



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termination events, including approval and sale of a generic form of TESTIM gel in the United States, in which case Auxilium is obligated to pay to us a specified percentage of the profits for product sales for the following two years. Also, we have been granted the exclusive option to co-promote any future Auxilium product candidate that treats male hypogonadism and contains testosterone as the active ingredient. The co-promotion agreement requires that the terms and conditions of any such future agreement be negotiated in good faith by the parties at the time the option is exercised.

### **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 will include 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. Although we cannot predict with certainty the costs necessary to complete this study, we currently estimate it will cost between \$7-8 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 October 2005 we submitted a supplemental New Drug Application with the FDA for approval to promote the five-day treatment of FACTIVE tablets for this indication. In January 2006, the FDA accepted our submission for filing. We expect the FDA to act on our application by the end of September 2006. There is no assurance that the FDA will approve our application.

#### **Ramoplanin**

We are developing a novel investigational antibiotic candidate, Ramoplanin, which is currently in development 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 control of Ramoplanin manufacturing, development and commercialization.

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. According to the agreement reached with the FDA, the required clinical development program will be comprised of two pivotal Phase III trials. The two non-inferiority studies will enroll, in each trial, approximately 490 patients diagnosed with CDAD, from centers in the United States, Canada and other parts of the world. Each patient will be randomly assigned to one of two treatment arms, in a double-blind fashion: Ramoplanin 200 mg twice daily or vancomycin 125 mg four times daily for ten days. The primary endpoint will be the response rate at end of therapy. We have recently engaged a contract research organization and started the process of assessing sites in advance of the start of the Phase III studies. We plan to commence the Phase III in the third quarter of 2006. Cost and timing related to such Phase III program will remain subject to numerous factors beyond our control, such as identifying centers and physicians to conduct the clinical trials, the pace of enrollment in clinical trials, possible regulatory delays of clinical trials and the strength of the data produced by a given trial. As a result of these factors, we are unable to determine the estimated completion date or the estimated cost to complete the Ramoplanin trial.

### **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:

#### **Revenue Recognition**



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Our principal source of revenue is the sale of FACTIVE tablets, which began shipping in the third quarter of 2004. In the second quarter of 2005, we began recognizing co-promotion revenue in connection with our agreement with Auxilium. 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 and co-promotion revenues will continue to increase based on anticipated increased volume of prescriptions of FACTIVE tablets and TESTIM testosterone gel.

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 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

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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 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, is classified as co-promotion revenue in our accompanying 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. 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.

### **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. We also maintained a genomics services business. 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 accompanying consolidated financial statements.

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.

Other revenues consist of sublicensing revenues related to FACTIVE related to Pfizer Mexico. We recognize revenue in accordance with Emerging Issues Task Force Issue No. 00-21, Revenue Arrangements with Multiple Deliverables (EITF No. 00-21). In accordance with EITF No. 00-21, the up-front payment related to the Pfizer Mexico license agreement will be recognized as revenue over the term of the Company's obligations under the agreement.

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

Our FACTIVE 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 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 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. Our product has a 36-month expiration period from the date of manufacturing into a tablet. At March 31, 2006 and December 31, 2005, our product return reserve was approximately \$824,000 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



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allowance against trade receivables. As of March 31, 2006 and December 31, 2005, the balance for cash discounts was approximately \$140,000 and \$50,000, respectively.

### *Rebates*

The liability for managed care rebates is calculated upon historical and current rebate redemption and utilization rates contractually submitted by each state. As of March 31, 2006 and December 31, 2005 the balance of the accrual for managed care rebates was approximately \$420,000 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, and changes, if any, from those estimates would not be material to the financial statements. As of March 31, 2006, there have been no material changes to our estimates in the periods presented.

### *Special Promotional Programs*

We have offered certain promotional incentives to date to our customers 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 Rebate Program*

During the first quarter of 2006, we initiated a sample card program whereby we offered an incentive to patients in the form of a free full-course sample card for FACTIVE. We have accounted for this program in accordance with EITF No. 01-09. We developed 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 in 2005. The program expired on March 31, 2006, at which point the balance of the liability for this sample card program was approximately \$2,606,000.

#### *Voucher Rebate Programs*

During the fourth quarter of 2005, we initiated a voucher rebate program whereby we offered mail-in rebates to retail consumers. We have accounted for this program in accordance with EITF No. 01-09. The liability we recorded for this voucher rebate program was based upon the historical rebate redemption rates for the similar completed program that we commenced in the first quarter of 2005. As of March 31, 2006 and December 31, 2005, the balance of the liability for this voucher program was approximately \$23,000 and \$93,000, respectively. The program will expire on April 30, 2006 and the balance will be adjusted for the actual redemption rate.

## **Clinical Trial Expense Accrual**

Our clinical development trials related to FACTIVE and Ramoplanin 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 three-month period ended March 31, 2006, we adjusted our accrual for clinical trial expenditures to reflect our most current estimate of liabilities outstanding to outside 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 we have 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. Inventories consist of FACTIVE raw material in powder form and work-in-process of approximately \$9,770,000 and \$9,770,000, and FACTIVE finished tablets of approximately \$3,139,000 and \$4,417,000, as of March 31, 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 March 31, 2006 and December 31, 2005, there was approximately \$1,079,000 and \$2,072,000, in FACTIVE sample product to be used for FACTIVE marketing programs, which is classified as an other current asset in the consolidated balance sheet.



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### **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 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.

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 March 31, 2006, we do not believe that any of our long-lived assets, goodwill, and other intangible assets are impaired.

### **Stock-Based Compensation**

Effective January 1, 2006, we adopted SFAS No. 123(R), *Share-Based Payment*, (SFAS No. 123R) using the modified prospective 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 three months ended March 31, 2006 includes (1) compensation cost for all share-based payments granted prior to, but not vested as of December 31, 2005, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, *Accounting for Stock-Based Compensation* 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 options. Results for prior periods have not been 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 March 31, 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 over a two to four year time period and options granted to non-employees vest 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 life 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 2 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 current offering period began January 1, 2006 and is scheduled to end 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 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. Upon adoption of SFAS 123R, we began recording stock-based compensation expense related to the ESPP.



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Our assumptions used in calculating the fair value of each stock 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 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 three month period ended March 31, 2006 was between 52.75% and 53.41%. 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 three month period ended March 31, 2006 was between 4.35% and 4.72%. The expected term of the stock award is based on the simplified method allowable under SAB 107, Share Based Payment. Accordingly, the expected term is presumed to be the midpoint between the vesting date and the end of the contractual term. Our expected life using the simplified method for the three month period ended March 31, 2006 was 5 to 6.25 years. We have not paid and do not expect to pay any dividends, therefore our dividend yield is assumed to be 0%.

The adoption of SFAS No. 123R increased our first quarter 2006 operating loss, net loss, and cash flows from operating activities by \$1,051,000 and basic and diluted net loss per share by \$0.01. 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 adoption of SFAS No. 123R did not affect operating loss, loss before income tax benefit, net loss, cash flow from operations, cash flow from financing activities or basic and diluted net loss per share during the three months ended March 31, 2005.

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 16.85% to all unvested options as of March 31, 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 March 31, 2006, we estimate there was \$8.0 million of total unrecognized compensation cost related to unvested share based awards. This cost is expected to be recognized over a weighted average period of 2.1 years. We expect approximately 4,333,000 in unvested options to vest at some point in the future. Options expected to vest is calculated by applying an estimated forfeiture rate to the unvested options.



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### **Results of Operations**

#### ***Three Month Period Ended March 31, 2006 and March 31, 2005***

##### ***Revenues***

Total revenues increased 178% to approximately \$10,973,000 for the three month period ended March 31, 2006 from approximately \$3,946,000 for the three month period ended March 31, 2005.

Product sales increased 136% to approximately \$9,246,000 for the three month period ended March 31, 2006 from \$3,912,000 for the three month period ended March 31, 2005 due to higher shipments of FACTIVE tablets during the first quarter of 2006.

Co-promotion revenue increased to \$1,545,000 for the three month period ended March 31, 2006 from \$0 for the three month period ended March 31, 2005 due to the introduction of co-promoting TESTIM during the second quarter of 2005.

Biopharmaceutical/other revenues increased to approximately \$182,000 for the three month period ended March 31, 2006 from approximately \$34,000 for the three month period ended March 31, 2005, reflecting revenues from legacy assets.

##### ***Costs and Expenses***

Total costs and expenses decreased 10% to approximately \$29,763,000 for the three month period ended March 31, 2006 from approximately \$33,207,000 for the three month ended March 31, 2005.

Cost of product sales increased 33% to approximately \$2,750,000 for the three month period ended March 31, 2006 from \$2,066,000 for the three month period ended March 31, 2005. The gross margin on product sales was approximately 70% and 47% for the three month periods ended March 31, 2006 and 2005. The improvement in margin during the three month period ended March 31, 2006 is due to higher volume of FACTIVE tablets shipped to wholesalers as a result of increased prescriptions written by primary care physicians. Included in the cost of product sales is approximately \$1,191,000 of amortization of intangibles assets associated with FACTIVE for each of the three month periods ended March 31, 2006 and 2005. The gross margin excluding amortization of intangible assets was approximately 83% and 78% for the three month period ended March 31, 2006 and 2005.

Research and development expenses include internal research and development expenses, strategic alliance partners, as well as clinical development costs and expenses. Research and development expenses primarily consist of salaries and related expenses for personnel and amortization of intangible assets. Other research and development expenses include fees paid to consultants and outside service providers, information technology and facilities costs. Research and development expenses decreased 51% to approximately \$2,928,000 for the three month period ended March 31, 2006 from approximately \$6,004,000 for the three month period ended March 31, 2005. The decrease in research and development expenses is due to a reduction of expenses related to the completion of the FACTIVE 5-day clinical study in 2005 of approximately \$1.9 million, a decrease in the technology transfer of FACTIVE of approximately \$726,000 and a decrease in stock based compensation expense of approximately \$786,000, offset by an increase of \$336,000 in connection with the continuation of the FACTIVE post-marketing study.

Selling and marketing expenses increased slightly to approximately \$20,445,000 for the three month period ended March 31, 2006 from \$20,108,000 for the three month period ended March 31, 2005. The slight increase in selling and marketing expenses is due to an increase in sales and marketing personnel and related costs of approximately \$83,000, an increase in other selling and marketing costs of approximately \$1,522,000 to promote TESTIM, an increase in stock-based compensation expense of approximately \$393,000, offset by a decrease in advertising and promotional costs of approximately \$1,661,000.

General and administrative expenses decreased 28% to \$3,640,000 for the three months period ended March 31, 2006 from \$5,029,000 for the three month period ended March 31, 2005. The decrease is due to a one-time, up-front payment of \$2 million incurred in the first quarter of 2005 to LG Life Sciences for an amendment to the license agreement, offset by an increase in stock-based compensation expense of approximately \$531,000 for the three month period ended March 31, 2006.

##### ***Other Income and Expense***

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Interest income decreased 20% to approximately \$696,000 for the three month period ended March 31, 2006 from approximately \$870,000 for the three month period ended March 31, 2005 reflecting lower cash balances offset by higher interest rate yields from investments.

Interest expense decreased slightly to approximately \$2,010,000 for the three month period ended March 31, 2006 from approximately \$2,044,000 for the three month period ended March 31, 2005. For the period ended March 31, 2006, interest expense primarily consisted of approximately \$1,337,000 related to the \$153 million of senior convertible notes issued in the second quarter of 2004, \$305,000 related to the issuance of \$22 million of convertible notes issued in connection with the Genesoft merger, \$205,000 related to amortization of deferred financing costs along with \$161,000 of non-cash interest expense related to the facility lease liability.

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We recorded gain on sale of fixed assets of approximately \$38,000 for the three month period ended March 31, 2005, primarily due to the sale of laboratory and computer in 2005, which were no longer used in operations.

We recorded income from the sale of intellectual property of \$2,500,000 for the three month period ended March 31, 2005, due to the sale of intellectual property related to the genomic sequence of an undisclosed pathogen to Wyeth in 2005.

## **Liquidity and Capital Resources**

Our primary sources of cash have been from the issuance of debt and equity securities, product discovery alliances, the sale of FACTIVE tablets and co-promotion revenues based on the sale of TESTIM.

As of March 31, 2006, we had total cash, cash equivalents, restricted cash and short-term marketable securities of approximately \$64,150,000, which includes approximately \$11,800,000 in restricted cash. In April 2006, we completed a private placement which resulted in gross proceeds of approximately \$35,935,000. We may 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. We believe that, under our current rate of investment in development and commercialization programs, our existing capital resources are adequate to support operations for the next 18 months. There is no assurance, however, that changes in our plans or events affecting our operations will not result in accelerated or unexpected expenditures.

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 remain at the same level as we continue to promote the sale of TESTIM and commercialize FACTIVE.

## ***Cash Flows***

Our operating activities used cash of approximately \$16,548,000 and \$30,416,000 for the three month periods ended March 31, 2006 and 2005, respectively. Cash used in our operating activities for three month period ended March 31, 2006 was primarily a result of our net loss of approximately \$20,104,000 and an increase in accounts receivable of approximately \$2,781,000 due to higher sales volume of FACTIVE tablets. Cash used in our operating activities was also a result of decreases in accounts payable of approximately \$957,000, clinical trial expense accrual of approximately \$292,000 related to the FACTIVE post marketing studies, accrued facilities impairment charge of approximately \$573,000 related to our west coast facility, and accrued restructuring charge of approximately \$111,000 related to our prior facility in Waltham, Massachusetts. These uses of cash were partially offset by increases in accrued expenses and other current liabilities of approximately \$2,632,000 related to higher accrued sales reserves and allowances related to a sample card promotional program, higher deferred revenue of approximately \$311,000, higher accrued other long term liabilities of approximately \$304,000 and decreases in interest receivable of approximately \$125,000 due to lower overall cash balances. Additional offsets include lower inventories balances of approximately \$1,255,000 due to higher shipments and lower prepaid expense and other current assets of approximately \$777,000 related to decreased prepaid marketing costs for the three month period ended March 31, 2006. Offsetting our operating uses of cash were non-cash depreciation and amortization expenses of approximately \$1,379,000, stock-based compensation of \$1,098,000, provision for excess and obsolete inventories of approximately \$23,000 as well as non-cash interest expenses of approximately \$366,000.

Cash used in our operating activities for three month period ended March 31, 2005 was primarily a result of our net loss of approximately \$27,857,000, increases in inventory of approximately \$2,981,000 due to anticipated increased demand of FACTIVE tablets in the second half of the year as well as prepaid expenses and other current assets of approximately \$2,485,000 related to an up-front payment to our contracted sales organization of approximately \$1,778,000 and prepaid business insurance and other expenses of approximately \$707,000. Cash used in our operating activities was also a result of decreases in accounts payable of approximately \$1,568,000, deferred revenues of approximately \$389,000 related to our initial stocking incentive program, accrued facilities impairment charge of approximately \$703,000 related to our west coast facility, and accrued restructuring charge of approximately \$511,000 related to our prior facility in Waltham, Massachusetts. These uses of cash were partially offset by increases in clinical trial expense accrual of approximately \$1,756,000 related to the clinical trial of FACTIVE for the 5-day treatment of CAP and post marketing studies, accrued expenses and other current liabilities of approximately \$1,514,000 related to higher accrued sales reserves and allowances of approximately \$1,042,000, higher accrued convertible note interest of approximately \$1,337,000, higher accrued other expenses of approximately \$203,000 and lower accrued payroll related expenses of approximately \$1,068,000. Offsetting our operating uses of cash were non-cash stock based compensation, depreciation and amortization expenses of approximately \$2,279,000 as well as non-cash interest expenses of approximately \$405,000.



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Our investing activities provided cash of approximately \$2,710,000 and \$45,056,000 for the three month periods ended March 31, 2006 and 2005, respectively. Cash provided by our investing activities for the three month period ended March 31, 2006 was primarily related to net proceeds from maturities of marketable securities of approximately \$2,696,000 and proceeds from notes receivable of approximately \$140,000. Cash provided from investing activities were partially offset by an increase in restricted cash of approximately \$70,000 and an increase in other assets of approximately \$56,000.

Cash provided by our investing activities for the three month period ended March 31, 2005 was primarily related to net proceeds from maturities of marketable securities of approximately \$46,665,000, proceeds from sales of property and equipment of approximately \$135,000 and a decrease in other assets of approximately \$14,000. Cash provided by investing activities were partially offset by the issuance of notes receivable of approximately \$1,387,000, purchases of property and equipment of approximately \$339,000 and an increase in restricted cash of approximately \$32,000.

Capital expenditures totaled approximately \$339,000 for the three month periods ended March 31, 2005 primarily consisting of purchases of computer and related equipment as well as office furniture and leasehold improvements for the new office facilities.

Our financing activities provided cash of approximately \$570,000 for the three month period ended March 31, 2006, primarily due to proceeds from exercise of 82,524 stock options of approximately \$122,000 and proceeds from the issuance of 232,110 shares of stock under the employee stock purchase plan of approximately \$448,000.

Our financing activities provided cash of approximately \$261,000 for the three month period ended March 31, 2005, primarily due to proceeds from exercise of 650,107 stock options of \$353,000 and proceeds from the issuance of 64,532 shares of stock under the employee stock purchase plan of \$200,000 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 \$377,305,000 and \$278,981,000 available to reduce federal and state taxable income respectively, if any. In addition, we also had tax research credit carryforwards of approximately \$20,045,000 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 and Equity Financings*

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 million, net of issuance costs.

On April 11, 2006, we closed a private placement of our common stock with institutional and other accredited investors pursuant to which we sold an aggregate of 18,035,216 shares of our common stock at a price of \$1.93 per share and warrants

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to purchase 9,017,608 shares of common stock at a price of \$0.125 per share of common stock issuable pursuant to such warrants. The warrants have an exercise price of \$2.22 per share and a term of five years.

### **Contractual Obligations**

For the three month period ended March 31, 2006, there were no material changes to our contractual obligations outside the ordinary course of business.

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

Our market risks, and the ways we manage them, are summarized under the captions "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Quantitative and Qualitative Disclosures About Market Risk", each included in our Form 10-K for the year ended December 31, 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.

## **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 \$88,593,000 for the fiscal year ended December 31, 2005 and had an accumulated deficit of approximately \$337,428,000. The losses have resulted primarily from costs incurred in research and development, including our clinical trials, 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.

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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 continue the co-promotion of TESTIM gel and in research and development in connection with clinical trials and formulation activities to support the existing labeling of FACTIVE tablets, the expansion of FACTIVE labeling claims and the development of Ramoplanin. In addition, our partners' product development efforts which 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.

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### **Our business will be very dependent on the commercial success of FACTIVE and TESTIM.**

FACTIVE tablets and TESTIM gel 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. TESTIM gel has been approved by the FDA for the treatment of male hypogonadism. The commercial success of FACTIVE and TESTIM 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 male hypogonadism, in the case of TESTIM gel. The commercial success of TESTIM gel is also dependent, in part, on the marketing and detailing efforts of Auxilium, which efforts are beyond our control. If FACTIVE and TESTIM are not commercially successful, we will have to find additional sources of funding or curtail or cease operations.

### **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 for the next 18 months. We will likely raise additional capital in the future to fund our operations, in particular, 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. 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, TESTIM 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, TESTIM and our other product candidates.**

FACTIVE tablets are our first FDA approved product. To date, we still have limited marketing and sales experience. The launch of FACTIVE occurred in September of 2004 and the co-promotion of TESTIM gel began in May 2005. The continued development of these marketing and sales capabilities, including the expansion of our sales force, will require significant expenditures, management resources and time. Further, as part of this development, we may seek to establish a co-promotion partnership in the future to expand FACTIVE commercialization in the U.S. or in our other licensed territories and/or acquire additional products for our expanded sales force. However, there is no assurance that we will be able to enter into a co-promotion agreement or acquire new products on favorable terms or at all. Failure to successfully establish sufficient sales and marketing capabilities in a timely and regulatory compliant manner or to find suitable sales and marketing partners may adversely affect our business and results of operations.

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

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<sup>®</sup> (levofloxacin), a product of Ortho-McNeil Pharmaceutical, Inc., and Cipro<sup>®</sup> (ciprofloxacin) and Avelox<sup>®</sup> (moxifloxacin), both products of Bayer Corporation;



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

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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.

The primary competition for TESTIM gel for the treatment of male hypogonadism is ANDROGEL®, marketed by Solvay Pharmaceuticals. ANDROGEL was launched approximately three years before TESTIM and, according to NDC, has a much larger share of the testosterone gel market than TESTIM gel accounting for approximately 56% of total testosterone prescriptions for the twelve months ending March 31, 2006. TESTIM gel also competes with other forms of testosterone replacement therapies, or TRT, such as oral treatments, patches, injectables and a buccal tablet. Generally, testosterone gels are more expensive than patches and injectables. ANDRODERM® is a transdermal testosterone patch marketed by Watson Pharmaceuticals. ANDRODERM is the leading patch product and accounted for approximately 10% of total testosterone prescriptions for the twelve months ending March 31, 2006. Other new treatments are being sought for TRT which may compete with TESTIM gel.

We are also aware that Watson Pharmaceuticals filed an abbreviated New Drug Application (ANDA) for generic ANDROGEL which was approved by the FDA on January 27, 2006. Par Pharmaceutical has also filed an ANDA with the FDA for generic ANDROGEL for which its partner, Paddock Laboratories, received tentative approval on November 1, 2004. Solvay Pharmaceuticals has filed patent infringement lawsuits against these two companies. In January 2006, the thirty-month stay in each patent action expired. If one of the companies chooses to market their product, this would result in increased competition for TESTIM, most likely at lower prices. Other pharmaceutical companies may develop generic versions of any products that we commercialize that are not subject to patent protection or other proprietary rights. Governmental and other cost containment pressures may result in physicians writing prescriptions for these generic products.

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, 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.

Additionally, we are aware that Vicuron and Novartis AG are jointly developing PDF inhibitor agents that may compete with any PDF products developed by our company.

All of our other internal product programs are in earlier stages and have not yet reached clinical development and are not yet indication specific. Our alliance-related product development programs are also all in preclinical stages, and it is therefore not possible to identify any product profiles or competitors for these product development programs at this time. Our industry is very competitive and it therefore is likely that if and when product candidates from our early stage internal programs or our alliance programs reach the clinical development stage or are commercialized for sale, these products will also face competition.

Many of our competitors will 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.

**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).



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The original owner of rights to FACTIVE in the U.S. submitted a New Drug Application for FACTIVE for the treatment of several indications, including ABS, and received a non-approvable letter in December 2000. In November of 2005, we submitted a supplemental New Drug Application (sNDA) to the FDA seeking approval for the use of FACTIVE for the five-day treatment of ABS and the five-day treatment of CAP. On January 19, 2006, the FDA accepted for filing our sNDA for five-day CAP but refused to accept the sNDA filing for ABS. Acceptance for filing of five-day CAP does not ensure approval. In its refusal to accept the sNDA filing for ABS, the FDA indicated that FACTIVE did not exhibit an acceptable risk versus benefit profile for the ABS indication. In addition, the FDA expressed the opinion that demonstrating an acceptable risk versus benefit profile for FACTIVE in ABS was not feasible, given the FDA's view of the potential risk of rash in those patients. As part of the process to address the FDA's concerns related to this indication, we met with officials at the FDA to continue the dialogue regarding appropriate subsequent actions. Following these discussions, we requested that the FDA file the sNDA over protest. The FDA has now filed the sNDA over protest and we expect a response from the FDA on the ABS sNDA by the end of 2006. Given the FDA's original decision to refuse to accept for filing the sNDA for the treatment of ABS, we cannot guarantee that the ABS indication will ever be approved by the FDA.

The FDA has granted a standard ten-month review period for the five-day CAP sNDA. We cannot be certain whether additional data will be required, if we will be required to conduct additional clinical trials or if the five-day CAP sNDA will ultimately be approved. In order to market FACTIVE for other indications, we may need to conduct additional clinical trials, obtain positive results from those trials and obtain FDA approval for such proposed indications. 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.

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

As part of our growth strategy, we intend to acquire, develop and commercialize additional product candidates or approved products. The success of this strategy depends upon our ability to identify, select and acquire 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.

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

### **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 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.

### **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, TESTIM, 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

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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

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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 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.

In addition, pharmaceutical companies have faced lawsuits and investigations pertaining to violations of 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. While we have developed and implemented a corporate compliance program based upon what we believe are current best practices, we cannot guarantee that this program will protect us from future lawsuits or investigations.

Failure to comply with or changes to the regulatory requirements that are applicable to FACTIVE, TESTIM 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, TESTIM or a product candidate from the market;

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

fines against us or our partners;

suspension or withdrawal of regulatory approvals for FACTIVE, TESTIM 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.

**Testosterone is classified by the U.S. Drug Enforcement Agency as a controlled substance and our failure or Auxilium's failure to comply with these heightened regulations could harm our business.**

TESTIM gel contains testosterone which is listed by the U.S. Drug Enforcement Agency, or DEA, as a Schedule III substance under the Controlled Substances Act of 1970. The DEA classifies substances as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. Scheduled substances are subject to DEA regulations relating to manufacturing, storage, distribution and physician prescription procedures. Auxilium must register annually with the DEA to manufacture, distribute, dispense, import, export, and conduct research using controlled substances. State controlled substance laws also require registration for similar activities. In addition, the DEA requires entities handling controlled substances to maintain records and file reports, follow specific labeling and packaging requirements, and provide appropriate security measures to control against diversion of controlled substances. Failure to follow these requirements can lead to significant civil and/or criminal penalties and possibly even lead to a revocation of a DEA registration.

In addition, products containing controlled substances may generate public controversy. As a result, these products may have their marketing rights or regulatory approvals withdrawn. Political pressures and adverse publicity could lead to delays in, and increased expenses for, and limit or restrict the marketing of TESTIM gel. Such delays, restrictions or expenses could harm our business.

**If testosterone replacement therapies are perceived to create or do create health risks, sales of TESTIM may be adversely affected.**

Recent studies of female hormone replacement therapy products have reported an increase in health risks. As a result of such studies, some companies that sell or develop female hormone replacement products have experienced decreased sales of these products, and in some cases, a decline in the value of their stock. Publications have, from time to time, suggested

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potential health risks associated with testosterone replacement therapy, or TRT. Potential health risks were described in various articles, including a 2002 article published in *Endocrine Practice* and a 1999 article published in the *International Journal of Andrology*. The potential health risks detailed were fluid retention, sleep apnea, breast tenderness or enlargement, increased red blood cells, development of clinical prostate disease, increased cardiovascular disease risk and the suppression of sperm production. It is possible that studies on the effects of TRT could demonstrate these or other health risks. This, as well as negative publicity about the risks of hormone replacement therapy, including TRT, could adversely affect patient or prescriber attitudes and impact TESTIM sales.

### **Sales of TESTIM will be highly dependent upon physician acceptance of testosterone replacement therapy for the treatment of hypogonadism.**

TESTIM gel is a testosterone replacement therapy, or TRT, approved for the treatment of hypogonadism, a disorder that affects approximately 20% of the U.S. male population over age 50. However, only about 5% of hypogonadal men currently receive TRT to treat their condition. Significant effort may be necessary to educate physicians, particularly primary care physicians, regarding the benefits of TRT for hypogonadal men. If TRT does not gain wider acceptance among physicians for the treatment of hypogonadism, the growth of TESTIM sales could be adversely affected.

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

We do not have the internal capability to manufacture pharmaceutical products. Under our agreement with LG Life Sciences, LG Life Sciences manufactures bulk quantities of the active pharmaceutical ingredient of FACTIVE, and we use Patheon to produce the finished FACTIVE tablets. The co-promotion agreement for TESTIM gel provides that Auxilium is responsible for the manufacture and distribution of TESTIM gel. TESTIM gel is currently manufactured for Auxilium by DPT Laboratories. Although the LG Life Sciences and DPT Laboratories facilities have previously been inspected by the FDA, future inspections may find deficiencies in the facilities or processes that may delay or prevent the manufacture or sale of our products.

Auxilium's contract with DPT Laboratories to manufacture TESTIM gel expires on December 31, 2010. Although Auxilium is currently in the process of qualifying a back-up supplier to manufacture TESTIM gel, there is currently no alternative manufacturer of TESTIM gel. If there is significant delay in qualifying this back-up supplier, there could be future supply shortages of TESTIM gel. Auxilium also relies on third party suppliers for their supply of testosterone and pentadecalactone, or CPD, two key ingredients of TESTIM gel. Testosterone is available to Auxilium from only two sources. Auxilium relies exclusively on one outside source for their supply of CPD. Auxilium does not have any agreements with these suppliers regarding these key ingredients. If either of the two sources that produce testosterone stops manufacturing it, or if Auxilium is unable to procure testosterone on commercially favorable terms, Auxilium may be unable to continue to produce TESTIM on commercially viable terms, if at all. In addition, if Auxilium's third-party source of CPD stops manufacturing pharmaceutical grade CPD, or does not make CPD available to Auxilium on commercially favorable terms, Auxilium may be unable to continue to produce TESTIM on commercially viable terms, if at all. Furthermore, the limited number of suppliers of testosterone and CPD may provide such companies with greater opportunity to raise their prices. Any increase in price for testosterone or CPD may reduce the gross margins on sales of TESTIM gel.

Pursuant to our recent 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 or a delay in the technology transfer from Vicuron, we could experience a supply shortage of Ramoplanin bulk drug, affecting our ability to complete the anticipated Phase III clinical program and/or begin commercialization of Ramoplanin.

We cannot be certain that LG Life Sciences, DPT Laboratories, Patheon 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. DPT Laboratories is currently the only qualified manufacturer of TESTIM gel. If these facilities are damaged or otherwise unavailable, we could incur substantial costs and delay in the commercialization of our products. 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





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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.

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

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. We have an exclusive arrangement with Integrated Commercial Solutions, Inc. (ICS) to perform such supply chain manufacturing services for a three-year period. Under our agreement with Auxilium, Auxilium provides all supply chain services for TESTIM gel.

We cannot be certain that ICS and Auxilium will be able to perform uninterrupted supply chain services. If ICS or Auxilium 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 tablets, 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 to wholesale drug distributors who generally sell products to retail pharmacies and other institutional customers. We do not promote FACTIVE to these wholesalers, and they do not determine FACTIVE prescription demand. However, approximately 81% of our product shipments during 2005 were to only two wholesalers. Our ability to commercialize FACTIVE tablets will depend, in part, on the extent to which we maintain adequate distribution of FACTIVE tablets via wholesalers, pharmacies and hospitals, as well as other customers. Although a majority of the larger wholesalers and retailers distribute and stock FACTIVE tablets, 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, the commercialization of FACTIVE 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 who we rely on 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 will 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.

We may not be able to maintain our existing arrangements with respect to the commercialization of our existing products, FACTIVE and TESTIM, or establish and maintain arrangements 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.

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

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

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

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

**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. We have engaged a contract clinical research organization and started the process of assessing sites in advance of the start of the Phase III studies. Prior clinical and preclinical trials for Ramoplanin were conducted by Vicuron and its licensees, from whom we acquired rights to Ramoplanin. We may not be able to complete future trials or make the filings within the timeframes we currently expect. If we are delayed in completing the trials or making the filings, 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. Further, depending upon our discussions with the FDA regarding the ABS indication, we may need to conduct additional trials. Such trials would entail significant time and expense and the FDA has indicated doubt as to the likelihood of their success. Additionally, clinical trials may 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;

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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.

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

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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.

### **Results related to post-marketing studies could restrict our ability to commercialize FACTIVE tablets.**

In December 2000, the FDA issued a non-approvable letter to the prior owner of rights to FACTIVE due, in part, to safety concerns arising out of an increased rate of rash relative to comparator drugs, especially in young women. While the FDA did approve FACTIVE tablets for marketing in April 2003, it 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 CAP or AECB. This study includes patients of different ethnicities to gain safety information in populations not substantially represented in the existing clinical trial program, specifically as it relates to rash. Patients will be evaluated for clinical and laboratory measures of safety. This Phase IV trial, with the approval from the FDA, was initiated in the second half of 2004. In connection with the approval of FACTIVE tablets, the FDA has also required us to perform a utilization study to obtain data on the prescribing patterns and use of FACTIVE tablets for the first three years after initial marketing in the U.S. As part of this requirement, we furnish interim reports to the FDA annually on the number of prescriptions issued, including refills, and the diagnoses for which the prescriptions are dispensed. The results of the Phase IV trial and the utilization study that we are required to provide to the FDA, as well as other safety information arising out of post-marketing safety surveillance, could restrict our ability to commercialize FACTIVE tablets.

### **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 69 issued U.S. patents, approximately 90 pending U.S. patent applications, 156 issued foreign patents and approximately 213 pending foreign patent applications. These patents and patent applications primarily relate to (1) the chemical composition, use, and method of manufacturing FACTIVE, (2) metalloenzyme inhibitors, their uses, their targets, (3) anti-infective compounds and their uses, and (4) the field of human and pathogen genetics. Our material patents are as follows:

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;

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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.

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.

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.

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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.

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.

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. 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

other companies may design around technologies we have licensed or developed.

### **We rely on Auxilium's license of Bentley Pharmaceuticals' intellectual property which provides limited patent protection for TESTIM.**

Currently, TESTIM gel is not covered by composition of matter patents. Testosterone, the active ingredient in TESTIM gel, is off-patent and is included in competing testosterone replacement therapy products. The U.S. patent that Auxilium licenses from Bentley Pharmaceuticals relates to a key component of the formulation of TESTIM gel and expires in June 2008. Bentley has filed a new patent application relating to the formulation in the U.S. which, if issued, could provide additional patent protection for TESTIM gel. Moreover, patent prosecution, maintenance and enforcement of the Bentley patent portfolio as it relates to TESTIM gel is controlled by Auxilium. Accordingly, we may be unable to exercise the same degree of control over this intellectual property as we would over our internally developed intellectual property or intellectual property which we directly license. Without additional patent protection, generic competition of TESTIM gel could adversely affect our sales. Furthermore, Auxilium's failure to perform under its license arrangement with Bentley could result in the termination of the license and our

ability to market TESTIM gel.

**We may infringe the intellectual property rights of third parties and may become involved in expensive intellectual property litigation.**

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.



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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 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.

### **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 the 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 agreement for FACTIVE, our co-promotion agreement for TESTIM and our sublicense agreement to Pfizer, S.A. de C.V., 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 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, relate 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

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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 ingredient for FACTIVE required by Pfizer Mexico in Mexico. We believe that, together with our manufacturing partners, we will be able to meet such supply and other obligations under the sublicense agreement but can make no assurances to that we will be able to remain in compliance with such responsibilities.

### *Auxilium*

On April 11, 2005, we entered into an agreement with Auxilium granting us the exclusive right to co-promote TESTIM gel to primary care physicians in the U.S. Under this agreement we are obligated to share TESTIM promotional expenses to this audience equally with Auxilium. The agreement also requires minimum levels of annual physician detailing which, if not met, would allow Auxilium to terminate the agreement. The initial term of the agreement ends on April 30, 2007. We may extend the agreement for two consecutive two-year periods provided that certain milestones related to physician detailing, market share and gross sales have been met by us for each extension period. We believe that we are currently in compliance with our obligations under the Auxilium 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 senior officers: Steven M. Rauscher, President and Chief Executive Officer; Stephen Cohen, 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 us.

Our future success is dependent upon our ability to attract and retain additional qualified sales and marketing, clinical development, scientific and managerial personnel. The launch of the commercial sale of FACTIVE tablets during the second half of 2004 required us to significantly increase our hiring of new employees, primarily with expertise in the areas of sales and marketing. We will continue to increase these efforts in the future. 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 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



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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 recently entered into a Sublicensing and Distribution Agreement with Pfizer, S.A. de C.V. (Pfizer Mexico) whereby we sublicensed our rights to sell FACTIVE tablets in Mexico to Pfizer Mexico. We intend to further market FACTIVE through distribution partners in most, if not all, of the other international markets for which we have a license to market the product. This will include the European Union and Canada. We may not be able to secure distribution partners at all, or those that we do secure, including our relationship with Pfizer Mexico, 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, Mexico and other foreign jurisdictions for which we have rights to market the product, 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 March 31, 2006, we had approximately \$180,044,000 of indebtedness outstanding (including accrued interest and excluding trade payables and accrued liabilities). The level of our indebtedness, among other things, could:

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

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;

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; or

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

If we experience a decline in revenues due to any of the factors described in this report or otherwise, 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.

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, TESTIM gel, 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. In addition, in December 2003 President Bush signed into law new Medicare prescription drug coverage legislation. While we cannot yet predict the impact the new legislation could have on our ability to commercialize FACTIVE tablets, TESTIM gel, Ramoplanin and any future products, the new legislation could adversely affect our anticipated revenues and results of operations, possibly materially.

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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, TESTIM gel, 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 TESTIM 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.

## **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 TESTIM;

the revenues that we may derive from the sale of FACTIVE tablets and TESTIM, 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;

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

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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 March 31, 2006 the closing price of our common stock as reported on the Nasdaq National Market ranged from a high of \$6.78 to a low of \$1.60. 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

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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 TESTIM;

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

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**

None

### **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None

### **ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

None



**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

<b>Exhibit No.</b>	<b>Description</b>
10.1	Sublicensing and Distribution Agreement dated as of February 6, 2006 by and between Oscient Pharmaceuticals Corporation and Pfizer, S.A. de C.V.*
10.2	Amendment No. 5 to License and Option Agreement between Oscient Pharmaceuticals Corporation and LG Life Sciences, Ltd. dated February 3, 2006.*
10.3	Assignment and Termination Agreement dated February 3, 2006 by and between Oscient Pharmaceuticals Corporation and Vicuron Pharmaceuticals Inc. *
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act.
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act.
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act.

\* Confidential information has been omitted from this exhibit and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request.

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**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/ Stephen Cohen  
Stephen Cohen  
Senior Vice President & Chief Financial Officer

(Principal Financial Officer)

May 10, 2006

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**OSCIENT PHARMACEUTICALS CORPORATION**

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