OSCIENT PHARMACEUTICALS CORP
Form 10-Q
May 10, 2005
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SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the Quarterly Period Ended: March 31, 2005

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

Commission File No: 0-10824

OSCIENT PHARMACEUTICALS CORPORATION

(Exact name of registrant as specified in its charter)

MASSACHUSETTS	**04-2297484**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification no.)**

1000 WINTER STREET, SUITE 2200

WALTHAM, MASSACHUSETTS 02451

(Address of principal executive offices) (Zip code)

Registrant s telephone number: (781) 398-2300

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes x 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	**76,568,759 Shares**
$0.10 PAR VALUE	Outstanding May 5, 2005

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OSCIENT PHARMACEUTICALS CORPORATION

INDEX TO FINANCIAL INFORMATION AND OTHER INFORMATION

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PART 1 FINANCIAL INFORMATION

OSCIENT PHARMACEUTICALS CORPORATION

CONSOLIDATED BALANCE SHEETS (UNAUDITED)

	March 31, 2005	December 31, 2004
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 79,665,503	$ 64,743,273
Marketable securities (held-to-maturity)	48,018,558	94,683,700
Marketable securities (available-for-sale)	225,000	225,000
Restricted cash	5,386,250	5,386,250
Interest receivable	1,066,100	1,708,360
Note receivable	291,968	
Accounts receivable, net	5,010,518	4,223,412
Inventory	14,896,537	11,915,881
Prepaid expenses and other current assets	8,383,874	5,898,546
Total current assets	162,944,308	188,784,422
Property and Equipment, at cost:		
Manufacturing and computer equipment	4,092,011	11,090,405
Equipment and furniture	1,072,255	1,849,350
Leasehold improvements	65,828	78,707
	5,230,094	13,018,462
Less accumulated depreciation	3,669,091	11,560,752
	1,561,003	1,457,710
Restricted cash	11,621,128	11,589,517
Long-term note receivable	1,095,447	
Other assets	5,641,582	5,859,116
Intangible assets, net	69,182,181	70,373,796
Goodwill	62,495,061	62,495,061
	$ 314,540,710	$ 340,559,622
LIABILITIES AND SHAREHOLDERS EQUITY		
Current Liabilities:		
Current maturities of long-term obligations	$	$ 291,667
Accounts payable	7,512,155	9,080,046
Accrued expenses and other current liabilities	16,354,599	14,840,543
Current portion of accrued facilities impairment charge	3,275,968	3,213,819
Current portion of accrued restructuring charge	1,003,739	1,250,153
Clinical trial expense accrual	4,541,048	2,785,161
Deferred revenue	912,128	1,301,607

Total current liabilities	33,599,637	32,762,996
Long-term Liabilities:		
Long-term obligations, net of current maturities	175,059,647	175,059,647
Noncurrent portion of accrued facilities impairment charge	15,597,954	16,160,969
Noncurrent portion of accrued restructuring charge	704,763	969,049
Other long-term liabilities	1,513,574	1,206,965
Shareholders Equity:		
Common stock, $0.10 par value - Authorized - 175,000,000 shares, Issued and Outstanding - 76,517,462 and 74,131,815 in 2005 and 2004 respectively	7,651,746	7,580,282
Additional paid-in-capital	357,316,345	356,834,921
Accumulated deficit	(276,671,821)	(248,835,424)
Deferred compensation	(68,135)	(1,016,783)
Note receivable from officer	(163,000)	(163,000)
Total shareholders equity	88,065,135	114,399,996
	$ 314,540,710	$ 340,559,622

See Notes to Consolidated Financial Statements

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OSCIENT PHARMACEUTICALS CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

	Three Months Ended	
	March 31, 2005	March 27, 2004
Revenues:		
Product sales	$ 3,911,539	$
Biopharmaceutical	33,911	1,661,145
Total revenues	3,945,450	1,661,145
Costs and expenses:		
Cost of product sales	2,065,754	
Research and development (1)	5,167,533	5,194,833
Selling, general and administrative (1)	25,024,594	3,624,991
Write-off of in-process technology		11,704,396
Restructuring charge		98,649
Stock-based compensation	948,648	564,579
Total costs and expenses	33,206,529	21,187,448
Loss from operations	(29,261,079)	(19,526,303)
Other income (expense):		
Interest income	869,851	192,057
Interest expense	(2,044,086)	(295,812)
Gain on sale of fixed assets	38,139	50,734
Income from sale of intellectual property	2,500,000	
Other income	39,850	
Net other income (expense)	1,403,754	(53,021)
Loss from continuing operations	(27,857,325)	(19,579,324)
Income from discontinued operations	20,928	100,000
Net loss	$ (27,836,397)	$ (19,479,324)
Loss from continuing operations per common share:		
Basic and diluted	$ (0.37)	$ (0.35)
Income from discontinued operations per common share:		
Basic and diluted	$ 0.00	$ 0.00
Net loss per common share:		
Basic and diluted	$ (0.37)	$ (0.35)

Weighted Average Common Shares Outstanding:		
Basic and diluted	75,905,833	56,150,083
(1) Excludes non-cash stock-based compensation as follows:		
Research and development	$ 836,383	$ 437,036
Selling, general and administrative	112,265	127,543
	$ 948,648	$ 564,579

See Notes to Consolidated Financial Statements.

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OSCIENT PHARMACEUTICALS CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

	Three Months Ended	
	March 31, 2005	March 27, 2004
Cash Flows from Operating Activities:		
Loss from continuing operations	$ (27,857,325)	$ (19,579,324)
Income from discontinued operations	20,928	100,000
Net loss	$ (27,836,397)	$ (19,479,324)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	1,329,923	1,029,904
Non-cash interest expense	405,497	113,374
Non-cash write-off of in process technology at merger		11,704,396
Gain on sale of fixed assets	(38,139)	(41,685)
Amortization of deferred compensation	948,648	1,013,180
Changes in assets and liabilities, net of acquisition		
Interest receivable	642,260	(749,504)
Accounts receivable	(787,106)	815,880
Inventory	(2,980,656)	
Prepaid expenses and other current assets	(2,485,328)	(823,520)
Accounts payable	(1,567,891)	26,529
Accrued expenses and other current liabilities	1,514,056	613,285
Clinical trial expense accrual	1,755,887	1,615,887
Deferred revenue	(389,479)	(425,257)
Accrued facilities impairment charge	(702,491)	(510,708)
Accrued restructuring charge	(510,700)	
Other long-term liabilities	306,609	166,681
Net cash used in operating activities	(30,395,307)	(4,930,882)
Cash Flows from Investing Activities:		
Cash flows related to acquisition		(14,989,074)
Purchases of marketable securities		(45,335,842)
Proceeds from maturities of marketable securities	46,665,142	2,832,000
Purchases of property and equipment	(338,104)	(84,292)
Proceeds from sale of property and equipment	134,642	48,900
Increase in restricted cash	(31,611)	
Decrease in other assets	13,662	1,625,684
Net cash provided by (used in) investing activities	46,443,731	(55,902,624)
Cash Flows from Financing Activities:		
Proceeds from sale of common stock		80,864,186
Proceeds from exercise of stock options	352,678	859,114
Proceeds from issuance of stock under the employee stock purchase plan	200,210	136,470
Payments on long-term obligations	(291,667)	(336,615)
Issuance of note receivable	(1,387,415)	

Net cash (used in) provided by financing activities	(1,126,194)	81,523,155
Net Increase in Cash and Cash Equivalents	14,922,230	20,689,649
Cash and Cash Equivalents, beginning of period	64,743,273	20,969,292
Cash and Cash Equivalents, end of period	$ 79,665,503	$ 41,658,941
Supplemental Disclosure of Cash Flow Information:		
Interest paid during period	$ 1,734	$ 15,757
Income tax paid during period	$	$ 989
Supplemental Disclosure of Non-cash Investing and Financing Activities:		
Deferred compensation related to unvested stock options at merger	$	$ 5,422,970
Notes receivable and accrued interest forgiven at merger	$	$ 6,268,795
Issuance of common stock related to merger	$	$ 74,878,945
Issuance of options and warrants in exchange of Genesoft s options and warrants	$	$ 19,533,549

See Notes to 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 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 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 financial statements and related footnotes for the year ended December 31, 2004 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 16, 2005.

(2) SUMMARY OF SIGNIFICANT BUSINESS AND ACCOUNTING POLICIES

Oscient Pharmaceuticals Corporation (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 its merger with GeneSoft Pharmaceuticals Inc. (Genesoft), a privately-held pharmaceutical company based in South San Francisco, California. The Company s product portfolio is led by the FDA-approved 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. In September 2004, the Company launched FACTIVE tablets. Additionally, the Company has two product candidates for the hospital marketplace in the United States currently in development.

The Company s hospital product portfolio includes a novel antibiotic candidate, Ramoplanin, which is currently in clinical development for the treatment of a serious hospital-acquired infection. Ramoplanin has been studied in a Phase II trial for the treatment of *Clostridium difficile*-associated diarrhea (CDAD) and the Company is currently in discussions with the FDA in connection with a special protocol assessment for the design of a Phase III program for the indication. Additionally, the Company has an intravenous formulation of FACTIVE in development, intended for use in hospitalized patients with pneumonia.

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 development and commercialization of the Company s own 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, which began shipping in the third quarter of 2004. Other sources of revenue include biopharmaceutical alliances and royalties from the divested genomic services business. In future periods, the Company expects its revenues derived from biopharmaceutical alliances will continue to decrease and product revenues will continue to increase based on anticipated increased volume of prescriptions of FACTIVE tablets and Testim, due to the Company entering into a co-promotion agreement with Auxilium Pharmaceuticals, Inc. on April 11, 2005 (See note 11).

Product Sales/Deferred Revenue

The Company follows the provisions of Staff Accounting Bulletin No. 104, Revenue Recognition (a replacement of SAB 101) and recognizes revenue from product sales upon delivery of product to wholesalers, when persuasive evidence of an arrangement exists, the fee is fixed or determinable, title to product and associated risk of loss has passed to the wholesaler and collectability of the

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related receivable is reasonably assured. All revenues from product sales are recorded net of applicable allowances for sales returns, rebates, chargebacks, 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 are recorded in inventory until such time as risk of loss has passed.

Sales Rebates, Discounts and Incentives

The Company s product sales are subject to various rebates, discounts and incentives that are customary in the pharmaceutical industry.

During the third quarter of 2004, the Company offered certain product stocking incentives to a number of pharmacy customers. These incentives included units with limited guaranteed sales provisions. As a result of these provisions, risk of loss of these units has not passed to the customer. Accordingly, the Company has deferred all revenue related to these units until such time as the unit is provided to a patient with a prescription. As of March 31, 2005, the remaining balance of deferred revenue related to these units is approximately $912,000.

Beginning in the fourth quarter of 2004, the Company initiated a sample card program whereby it offered an incentive to patients in the form of a free full-course sample card. The Company has accounted for this program in accordance with Emerging Issues Task Force Issue No. 01-09, Accounting for Consideration Given by a Vendor to a Customer (EITF No. 01-09). As of March 31, 2005, the Company did not have sufficient history with these types of incentive programs in order to develop a reasonable and reliable estimate of the amount of reimbursement claims that it expects to realize. As a result, the Company has recorded the maximum liability (100% redemption) for reimbursement claims related to sample cards distributed as of March 31, 2005 which resulted in a reduction of revenues. The liability related to unclaimed cards was approximately $1,824,000 as of March 31, 2005. The Company will adjust the liability upon completion of the program, which will result in additional product revenue being recorded at that time. The sample card program is expected to be completed in the second half of 2005 and the Company may be able to consider the actual redemption rate in estimating the liability for similar programs in the future.

During the first quarter of 2005, the Company initiated a voucher rebate program whereby it offered a rebate to patients who received a FACTIVE prescription. The Company has accounted for this program in accordance with EITF No. 01-09. As of March 31, 2005, the Company was able to develop a reasonable estimate of the liability for this program based upon historical redemption rates for similar completed programs offered by third parties. As of March 31, 2005, the reserve balance associated with the voucher rebate program was approximately $101,000. This program is expected to continue through at least the first half of 2005.

The Company s product sales are made to pharmaceutical wholesalers for further distribution through pharmacies to the ultimate consumers of our product. All revenues from product sales are recorded net of applicable allowances for returns, wholesaler chargebacks, cash discounts, and administrative fees. The Company estimates wholesaler chargebacks, cash discounts, administrative fees and other rebates by considering the following factors: current contract prices and terms, estimated customer and wholesaler inventory levels and current average chargeback rates. The process to estimate product returns includes the remaining shelf life and the product life cycle stage. The Company estimates product return allowances based on historical information for similar or competing products in the same distribution channel. Also, the Company obtains and evaluates product return data from distributors and, based on this evaluation, estimates return rates. The reserves are reviewed at each reporting period and adjusted to reflect data available at that time. The Company has accrued approximately $406,000 in sales return reserves and $544,000 in other revenue reserves as of March 31, 2005. To the extent the Company s estimates of contractual allowances, rebates and sales returns are different from actuals, the Company adjusts the reserve which impacts the amount of product sales revenue recognized in the period of the adjustment. The Company has not received any significant returns through March 31, 2005.

Biopharmaceutical Revenue

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

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(b) Restricted Cash

The Company s restricted cash 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, 2005 one payment of $2,302,000 had been made for which the cash restriction was released. In addition, approximately $4,130,000 of cash is restricted in connection with letters of credit issued for the building leases at the Company s Waltham, Massachusetts and South San Francisco, California facilities. The restrictions related to the building leases lapse at various dates through March 31, 2012.

(c) 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 lesser of the term of the lease or the estimated useful life of the assets.

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

Depreciation expense was approximately $138,000 and $316,000 for the three-month periods ended March 31, 2005 and March 27, 2004, respectively.

(d) Inventory

Inventory is stated at the lower of cost or market with cost determined under the first-in, first-out (FIFO) method. Inventory consists of raw material, labor and overhead charges as of March 31, 2005. As of March 31, 2005, inventory consists of FACTIVE raw material in powder form and work-in-process of approximately $7,255,000 and FACTIVE finished tablets of approximately $7,641,000 to be used for samples and commercial sales of FACTIVE. On a quarterly basis, the Company analyzes its inventory levels, and writes down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory that is in excess of

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expected requirements to cost of product revenues. Expired inventory will be disposed of and the related costs will be written off. Through March 31, 2005, there has been no write-down of inventory. The following table represents inventories:

	March 31, 2005
Raw Material	$ 3,820,247
Work-in-process	3,434,840
Finished Goods	7,641,450
Total	$ 14,896,537

Included in the table above is $6,720,898 of inventory that relates to validation lots of finished FACTIVE tablets and active pharmaceutical ingredients for FACTIVE that are not yet saleable until FDA acceptance of the technology transfer to Patheon, the Company s manufacturing partner.

(e) Net Loss Per Share

Basic and diluted net loss per share was determined by dividing net loss by the weighted average shares outstanding during the period. Diluted loss per share is the same as basic loss per share for all periods presented, as the effect of the potential common stock is 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 38,464,647 and 10,553,384 shares of the Company s common stock during the three-month periods ended March 31, 2005 and March 27, 2004, respectively.

(f) Single Source Suppliers

The Company currently obtains the active pharmaceutical ingredient for its commercial requirements for FACTIVE from single or limited sources. 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 these sources could have a material adverse effect on the Company s business, financial position and results of operations.

(g) Concentration of Credit Risk

SFAS No. 105, Disclosure of Information about Financial Instruments with Off-Balance-Sheet Risk and Financial Instruments with Concentrations of Credit Risk, requires disclosure of any significant off-balance-sheet and credit risk concentrations. The Company has no off-balance-sheet or concentrations of credit risk 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 nonaffiliated institutions.

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

	Number of Significant Customers	Percentage of Total Revenues by Customer				
		A	B	C	D	E
Three months ended:						
March 31, 2005	2	68%	15%			
March 27, 2004	2				55%	38%

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 accounts receivable:

	Number of Significant Customers	Percentage of Total Accounts Receivable by Customer				
		A	B	C	D	E
As of:						
March 31, 2005	3	60%	19%	10%		
December 31, 2004	3	49%	14%	22%		

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

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(h) Use of Estimates

The preparation of consolidated condensed 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.

(i) Reclassifications

The Company has reclassified certain prior-year information to conform with the current year s presentation.

(j) Change in Quarterly Reporting Periods

Beginning in 2005, the Company changed its quarter month end reporting dates to end on March 31, June 30 and September 30 as opposed to a thirteen week period end. The change in quarterly reporting dates does not have a material impact on the financial statements.

(k) Comprehensive Income (Loss)

The Company follows the provisions of SFAS No. 130, Reporting Comprehensive Income. 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 in marketable securities. For both three-month periods ended March 31, 2005 and March 27, 2004, the Company s net loss equaled comprehensive loss.

(l) Segment Reporting

The Company follows the provisions of SFAS No. 131, Disclosures about Segments of an Enterprise and Related Information. SFAS No. 131 establishes standards for reporting information regarding operating segments in annual financial statements and requires selected information for those segments to be presented in interim financial reports issued to stockholders. SFAS No. 131 also establishes standards for related disclosures about products and services and geographic areas. Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions as to how to allocate resources and assess performance. The Company s chief decision makers, as defined under SFAS No. 131, are the chief executive officer and chief financial officer. 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. As a result, the Company believes it now operates in one segment called biopharmaceutical and product sales and the financial information disclosed herein represent 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 prior 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. All of the Company s revenues are generated in the United States and all assets are located in the United States.

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(m) Pro Forma Disclosure of Stock-based Compensation

The Company applies the intrinsic value method under APB No. 25 and related interpretations, in accounting for its stock-based compensation plans, 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 Emerging Issues Task Force (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, 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 following table illustrates the effect on net loss and net loss per share if the Company had applied the fair value recognition provisions of SFAS No. 123 to employee stock-based compensation. The Company has computed the pro forma disclosures required under SFAS No. 123 and SFAS No. 148, Accounting for Stock-Based Compensation-Transaction and Disclosure, for all employee stock options granted using the Black-Scholes option pricing model prescribed by SFAS No. 123.

	Three Months Ended	
	March 31, 2005	**March 27, 2004**
Net loss as reported	$ (27,836,397)	$ (19,479,324)
Add: Stock-based employee compensation cost, included in the determination of net loss as reported	948,648	564,579
Less: Total stock-based compensation expense determined under the fair value method for all employee awards	(1,713,678)	(2,885,358)
Pro forma net loss	$ (28,601,427)	$ (21,800,103)
Basic and diluted net loss per share		
As reported	$ (0.37)	$ (0.35)
Pro forma	$ (0.38)	$ (0.39)

The Company s stock option grants typically vest over several years and the Company intends to grant varying levels of stock options in future periods. Therefore, the pro forma effects on net loss and net loss per common share of expensing the estimated fair value of stock options and common shares issued pursuant to the stock option plan for the three month periods ended March 31, 2005 and March 27, 2004 are not necessarily representative of the effects on reported results from operations for future years.

(n) Recent Accounting Pronouncements

Stock Based Compensation

On December 16, 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 123 (revised 2004), Share-Based Payment (SFAS No. 123(R)), which is a revision of SFAS No. 123, Accounting for Stock-Based Compensation (SFAS No. 123). SFAS No. 123(R) supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees (APB No. 25), and amends SFAS No. 95, Statement of Cash Flows . Generally, the approach in SFAS No. 123(R) is similar to the approach described in SFAS No. 123. However, SFAS No. 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. On April 14, 2005, the Securities and Exchange Commission delayed the effective date of SFAS No. 123(R) to the beginning of the first fiscal year ending after June 15, 2005. As a result, the Company expects to adopt SFAS No. 123 on January 1, 2006.

SFAS No. 123(R) permits public companies to adopt its requirements using one of two methods:

A modified prospective method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS No. 123(R) for all share-based payments granted after the effective date and (b) based on the requirements of SFAS No. 123 for all awards granted to employees prior to the effective date of SFAS No. 123(R) that remain unvested on the effective date.

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A modified retrospective method which includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under SFAS No. 123 for purposes of pro forma disclosures either (a) all prior periods presented or (b) prior interim periods of the year of adoption.

The Company is still assessing the method of adoption and model and is assessing the impact that the adoption of SFAS No. 123(R) will have on its results of operations and related disclosures. SFAS No. 123(R) will likely affect the Company s stock option issuances and shares purchased by employees under the employee stock purchase plan.

(3) MERGER WITH GENESOFT PHARMACEUTICALS, INC. AND SALE OF COMMON STOCK

On February 6, 2004, the Company completed its acquisition of Genesoft, a privately-held company located in South San Francisco, California pursuant to which, among other things, the Company acquired the rights to commercialize FACTIVE as the Company focused on expanding the business in the primary care physician market in the United States. The acquisition was accounted for as a purchase in accordance with SFAS No. 141, Business Combinations and accordingly, the Company allocated the purchase price of Genesoft based on the estimated fair value of net assets acquired and liabilities assumed. The purchase price of approximately $110 million was paid by the issuance of approximately 25.2 million shares of the Company s common stock to existing Genesoft common stockholders and promissory note holders and the issuance of options to purchase approximately 3.4 million shares for Genesoft stock options and warrants assumed in the merger. In connection with the merger, the Company assumed approximately $22 million in Genesoft debt, through the issuance of 5% convertible promissory notes. Such notes are convertible, at the option of the holder, into shares of the Company s common stock at a price of $6.6418 per share.

Concurrent with the merger, the Company sold 16.8 million shares of its common stock at $5.25 per share resulting in net proceeds received of approximately $81 million.

At the time of acquisition, 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 $18,328,000, which includes $1,419,000 in severance-related costs and $16,887,000 in facility lease impairment costs. In the quarter ended December 31, 2004, in accordance with 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 2004, the Company paid approximately $1,419,000 against the 2004 accrual for termination benefits.

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The following table displays the restructuring liability activity in 2005 as part of purchase accounting related to the Genesoft acquisition:

	Balance at December 31, 2004	Cash Payments	Interest Accretion	Balance at March 31, 2005
Facility lease liability	$ 19,374,788	$ (702,491)	$ 201,625	$ 18,873,922

The Company recorded interest expense of approximately $202,000 in the first quarter of 2005 in connection with the amortization of the lease liability. The Company recorded the lease liability at its net present value and, accordingly, the Company recorded interest expense associated with the amortization of this liability.

Additionally, the Company recorded approximately $5,423,000 of deferred compensation related to the intrinsic value of unvested options issued in exchange for options assumed in the merger, which was fully amortized through March 31, 2005.

(4) RESTRUCTURING PLANS

In the fourth quarter of 2004, the Company relocated its corporate headquarters from one facility in Waltham, Massachusetts to a different facility in Waltham, Massachusetts. The Company completed the relocation to obtain additional administrative space that was needed to support the launch of FACTIVE. As a result of the relocation, the Company recorded a restructuring charge of approximately $4.7 million. The total charge was comprised of $2.7 million for the value of rental costs that will continue to be incurred through the lease expiration date on November 15, 2006, net of expected sublease income 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 liability activity in the quarter ended March 31, 2005 as part of the restructuring plan:

	Balance at December 31, 2004	Cash Payments	Balance at March 31, 2005
Facility lease liability	$ 2,219,202	$ (510,700)	$ 1,708,502

(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, 2005 and December 31, 2004, the Company s investments included short-term marketable securities, the majority of which are classified as held-to-maturity, as the Company has the positive intent and ability to hold these securities to maturity. Cash equivalents are short-term, highly liquid investments with original 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 market value, and consist of debt securities. Marketable securities that are classified as held-to-maturity are recorded at amortized cost, which approximates market value and consist of commercial paper and U.S. government debt securities. At March 31, 2005, the average maturity of the Company s investments was approximately 3.1 months. Also, at March 31, 2005, the Company had a net unrealized loss of approximately $172,000, which is the difference between the amortized cost and the fair value of the held-to-maturity investments.

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At March 31, 2005 and December 31, 2004, the Company s cash and cash equivalents and investments consisted of the following:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
March 31, 2005				
Cash and Cash Equivalents:				
Cash	$ 69,842,874	$	$	$ 69,842,874
Debt securities, government and agency issues	2,496,467		(367)	2,496,100
Debt securities, corporate obligations	7,326,162	229	(204)	7,326,187
Total cash and cash equivalents	$ 79,665,503	$ 229	$ (571)	$ 79,665,161
Investments (held-to-maturity):				
Short-term debt securities, corporate securities	$ 48,018,558	$	$ (171,547)	$ 47,847,011
Investment (available-for-sale):	$ 225,000	$	$	$ 225,000
December 31, 2004				
Cash and Cash Equivalents:				
Cash	$ 57,635,695	$	$	$ 57,635,695
Debt securities, government and agency issues	2,484,967	1,283		2,486,250
Debt securities, corporate obligations	4,622,611		(2,688)	4,619,923
Total cash and cash equivalents	$ 64,743,273	$ 1,283	$ (2,688)	$ 64,741,868
Investments (held-to-maturity):				
Short-term debt securities, government and agency issues	$ 2,484,967	$ 1,283	$	$ 2,486,250
Short-term debt securities, corporate securities	92,198,733	3,769	(236,693)	91,965,809
Total investment (held-to-maturities)	$ 94,683,700	$ 5,052	$ (236,693)	$ 94,452,059
Investment (available-for-sale):	$ 225,000	$	$	$ 225,000

(6) NOTE RECEIVABLE

In connection with a lease agreement associated with vehicles for the Company s sales representatives, the Company was required to make a deposit as the vehicles were delivered. The amount of the deposit is in the form of a note receivable which bears interest at 5.5%. Principal and interest are paid back to the Company as lease payments are made on the vehicles.

(7) LONG-TERM OBLIGATIONS

On February 6, 2004, in connection with the merger with Genesoft, the Company issued $22,309,647 in principal amount of our 5% convertible five-year promissory notes. These notes are convertible into our common stock at the option of the holders, at a conversion price of $6.6418 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 our common stock representing the payment of accrued interest and related amounts on certain outstanding notes previously issued to them by Genesoft.

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In the quarter ended June 26, 2004, the Company issued $152,750,000 in principal amount of our 3.5% senior convertible promissory notes due in April 2011. These notes are convertible into our common stock at the option of the holders at a conversion price of $6.64 per share. The Company may not redeem the notes at its election 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 will be amortized 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, which are classified as restricted cash on the December 31, 2004 consolidated balance sheet. 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.

(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 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. This agreement has subsequently been 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 expires in 2019. 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. LG Life Sciences is expected to supply the FACTIVE bulk drug substance from its manufacturing facility in South Korea. The Company has initiated a technology transfer process with Patheon, including a CBE30 submission in April 2005 for the manufacture of finished products, to replace the previous fill and finish provider, SB Pharmco. The Company estimates that Patheon will obtain the necessary FDA qualifications to be the fill and finish provider during the first half of 2005. The Company expects that the quantities of FACTIVE tablets currently on hand, in combination with the quantities to be delivered from SB Pharmco (under its current obligations), will provide us with sufficient inventory until the new provider can be qualified. The current validation batches and other finished tablets at Patheon are expected to be available for commercial use during the second quarter of 2005. At March 31, 2005, the amount of inventory on hand includes $6,720,898 that relates to validation lots and active pharmaceutical ingredients that are not yet saleable until the FDA approves the technology transfer to Patheon.

The agreement also requires the Company to achieve a minimum level of FACTIVE sales over a period of time, which if not met, would result in the technology being returned to LG Life Sciences. Under this agreement, the Company is responsible, at its expense and through consultation with LG Life Sciences, for the clinical and commercial development of gemifloxacin in the countries covered by the license, including the conduct of clinical trials, the filing of drug approval applications with the FDA and other applicable regulatory authorities and the marketing, distribution and sale of gemifloxacin in our territory; provided, that LG Life Sciences has the right to co-promote the product, on terms to be negotiated, in our territory for 2008 and periods commencing thereafter, in which case our 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.

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Under this license agreement, the Company was required to pay LG Life Sciences $8 million upon the completion of the merger with Genesoft. This amount was accounted for as part of the purchase price for Genesoft. The Company is obligated to pay a royalty on sales of FACTIVE in the U.S. and the territories covered by the license in Europe. The royalty is fixed at a nominal rate during the first two years of commercial sales and increases thereafter. 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.

On March 31, 2005, the Company amended its license and option agreement with LG Life Sciences which included a reduction of future royalties payable to LG Life Sciences at higher revenue levels for FACTIVE in territories covered by the agreement. The amended agreement includes a $2 million license fee payable to LG Life Sciences upon execution of the amendment, which was recorded to general and administrative expense in the quarter end March 31, 2005. In addition, the agreement requires milestone payments of up to $30 million upon obtainment of additional regulatory approvals and certain sales thresholds.

(9) OTHER RESEARCH AND DEVELOPMENT

Prior to the merger with Genesoft, the Company conducted genomics-based research internally and through alliance partnerships with pharmaceutical companies and government grants. The Company also maintained a genomics services business. The Company has now transitioned its focus to development and commercialization of pharmaceutical products.

Research and development expenses have primarily consisted of salaries and related expenses for personnel and the cost of materials and supplies used in research and development. Other research and development expenses have included fees paid to consultants and outside service providers, information technology and facilities costs. The Company has charged all research and development expenses to operations as incurred. The research and development expenses related to biopharmaceuticals revenues generally consisted of sequencing services and related research activities for its alliance partners and government grants. The Company s revenue recognition policy for the funding received for these services and research activities is disclosed in the Company s policy discussed in Note 2(a).

The Company has tracked actual costs related to each of its government grants, but it has not tracked actual costs related to each of its alliances or its internal research and development programs, and as a result, this information is not available. The Company has, however, tracked total costs in the aggregate for its alliance and government grant arrangements separately from its internal research and development programs. During the three-month periods ended March 31, 2005 and March 27, 2004, the Company incurred expenditures of approximately $63,000 and $683,000, respectively, related to its alliances and government contracts.

(10) STOCKHOLDER S EQUITY

During the three months ended March 31, 2005, the Company issued 714,460 shares of its common stock pursuant to exercises of stock options and purchases under its employee stock purchase plan.

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The Company has completed its obligations under its alliances with Schering-Plough, bioMerieux and Wyeth in order to discover, research, develop and commercialize products. Revenues earned by the Company generally included an upfront license fee, sponsored/contract research payments and research and development and regulatory approval milestone payments. Potential revenues for the Company include future regulatory approved milestones and royalties. The Company s ability to earn those future milestone and royalty payments depends primarily upon whether our alliance partner identifies any compounds, through high-throughput screening and lead optimization, that warrant clinical development, whether any such compounds demonstrate the required safety and efficacy in clinical trials in order to support a regulatory approval and whether they are able to successfully manufacture and commercialize the product. It is uncertain whether the Company will earn those milestone and royalty payments due to numerous factors, including the risk of failure inherent in complex research and development programs, potential delays in clinical trials, negative, inconclusive or insufficient clinical data or the emergence of superior competitor products that may lead to abandonment of the program. The Company has not recognized any royalty revenue to date under these arrangements.

In December 2002, the Company entered into a strategic alliance with Amgen, Inc. to identify and develop novel therapeutic agents for bone diseases, including osteoporosis. In January 2004, both companies agreed to conclude the research collaboration effective April 7, 2004. With the conclusion of this research program, the Company retained certain intellectual property and licensing rights related to its gene discovery. Under this alliance, the Company received approximately $5.8 million through March 31, 2005, consisting of $5.3 million in research payments, a milestone payment and a license fee and $500,000 in an equity investment in the Company by Amgen. The Company recognized $0 and approximately $960,000 in revenue during the three-month periods ended March 31, 2005 and March 27, 2004, respectively, which consisted of alliance research revenue and amortization of the up-front license fee.

(11) SUBSEQUENT EVENTS

On April 11, 2005, the Company entered into a co-promotion partnership with Auxilium Pharmaceuticals, Inc. (Auxilium) to co-promote Auxilium s marketed product, Testim® 1% testosterone gel, for the treatment of hypogonadism in the United States. Under the terms of the agreement, the Company will promote Testim to primary care physicians utilizing its 250-person sales force beginning May 2005. Both companies will share profits from primary care sales above a predetermined baseline after marketing expenses are reimbursed. The co-promotion partnership has an initial term of two years and may be extended for up to six years, pending achievement of mutually agreed upon milestones.

Also, on April 27, 2005 the Company was informed that Agencourt Bioscience Corporation (Agencourt) entered into an agreement in which all of Agencourt s outstanding stock will be acquired by Beckman Coulter in exchange, all or in part, for cash. The Company owns common stock in Agencourt and the acquisition is expected to close by the end of the second quarter of 2005. The Company is unable to determine the amount of cash or other value it will receive until the transaction has been completed.

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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 loses and the Company s potential for profitability, the sufficiency of our cash resources, the relative levels of the Company s expenses for the remainder of 2005, future revenues and sales of FACTIVE and Testim, our intent to focus in the near term on the commercial and clinical development of FACTIVE and the sale of Testim, the hiring of sales and marketing personnel, our discount and rebate programs for FACTIVE, the outcome of our discussions with Vicuron regarding the filing of an NDA for Ramoplanin, the qualification of alternative manufacturers for our products, the timing of the filing of an NDA for FACTIVE for the treatment of ABS, as well as other statements related to the progress and timing of product development, present or future licensing, collaborative or financing arrangements or that otherwise relate to future periods, are forward-looking statements as defined by the Private Securities Litigation Reform Act of 1995. These statements represent, among other things, the expectations, beliefs, plans and objectives of management and/or assumptions underlying or judgments concerning the future financial performance and other matters discussed in this document. The words may, will, should, plan, believe, estimate, intend, anticipate, project, and expect and similar expressions are intended to identify forwa 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 include, but are not limited to:

- risks related to the successful commercialization of FACTIVE tablets, such as (i) our inability to successfully market the product due to competition from other drugs, (ii) our inability to recruit and retain a successful sales management team and sales force, (iii) lack of acceptance of the product by physicians, patients and third party payors, (iv) inability to obtain adequate distribution in wholesalers and pharmacies, and (v) problems related to manufacture or supply;

- risks related to our clinical development programs for our lead product candidate, Ramoplanin, and our programs to expand the approved indications for FACTIVE tablets, such as negative, inconclusive or insufficient results in ongoing or future clinical trials, FDA requests for additional information or data, delays in the progress of ongoing clinical trials and safety concerns arising with respect to our products or product candidates;

- our history of operating losses and our need to raise future capital to support our commercial activities, product development and research initiatives;

- intensified competition from pharmaceutical or biotechnology companies that may have greater resources and more experience than us;

- our inability or the inability of our alliance partners to obtain or enforce our intellectual property rights;

- our inability or the inability of our alliance partners to successfully develop and obtain regulatory approval of products discovered based on our previous genomics-based research; and

- our dependence on key personnel.

We have included more detailed descriptions of these and other risks and uncertainties under the heading Risk Factors below. We encourage you to read those descriptions 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 biopharmaceutical company committed to the clinical development and commercialization of new therapeutics to serve unmet medical needs.

On February 6, 2004, we completed our merger with GeneSoft Pharmaceuticals, Inc., a privately-held pharmaceutical company based in South San Francisco, California. The merger was accounted for as a purchase by us under accounting principles generally accepted in the United States. Under the purchase method of accounting, we are considered the acquirer and the assets and liabilities of Genesoft were recorded, as of the date of the merger, February 6, 2004, at their respective fair values and added to those of our Company. Reported financial condition and results of operations of our Company issued after February 6, 2004 reflect Genesoft s

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balances and results of operations after completion of the merger, but have not been restated retroactively to reflect the historical financial position or results of operations of Genesoft. Following February 6, 2004, the earnings of the combined company reflect purchase accounting adjustments, including in-process research and development charges and amortization and depreciation expense for acquired tangible and intangible assets. The most significant of the intangible assets identified have finite lives and relate to FACTIVE. These amounts will be amortized over their expected useful lives. Goodwill has also been recorded; however, pursuant to SFAS No. 141, Business Combinations and SFAS No. 142, Goodwill and Other Intangible Assets, goodwill will not be amortized but subjected to annual impairment review.

Our lead product is the fluoroquinolone antibiotic FACTIVE (gemifloxacin mesylate) tablets, indicated for the treatment of community-acquired pneumonia of mild-to-moderate severity and acute bacterial exacerbations of chronic bronchitis. The commercial sale of FACTIVE began in September 2004. For the near term, we intend to focus our efforts on commercial sales of FACTIVE tablets for these indications, commercial sales of Testim as well as clinical trials for other indications of FACTIVE.

We completed the initial recruitment of over 100 sales and marketing professionals in September 2004 to launch the sale of FACTIVE tablets and completed the hiring of an additional 150 sales and marketing professionals to support a nationwide sales force for FACTIVE during the quarter ended March 31, 2005.

In addition, we are developing a novel investigational antibiotic candidate, Ramoplanin, which is currently in clinical trials for the treatment of a serious hospital-acquired infection. On August 10, 2004, we announced preliminary results of our Phase II trial of Ramoplanin for the treatment of *Clostridium difficile*-associated diarrhea (CDAD). Pending discussions with the FDA, regarding a Special Protocol Assessment, which was submitted in late 2004 and completion of discussions on timing of the clinical development program with our partner, Vicuron, the program will be ready to commence a Phase III trial.

In past fiscal years, we also received revenues from our genomics services business from selling, as a contract service business, high quality genomic sequencing information to our customers. As part of our continued evolution into a product-focused, commercial stage biopharmaceutical company, on March 14, 2003, we completed the sale of our genomics services business to privately held Agencourt Bioscience Corporation (Agencourt). As part of the agreement, we transferred our sequencing operations, including certain equipment and personnel to Agencourt. We received an up-front cash payment of $200,000 and shares of Agencourt s common stock. We will also receive a percentage of revenues from our former commercial and government customers, transferred to Agencourt, for a period of two years from the date of sale. We retain rights to our PathoGenome Database product, including all associated intellectual property, subscriptions and royalty rights on products developed by subscribers. As of March 31, 2005, we have received a total of approximately $750,000 from Agencourt since March 14, 2003 (See Note 11 in the accompanying consolidated financial statements).

Previously, we received payments from our product discovery alliances based on license fees, contract research and milestone payments during the term of our alliances. Our alliances could result in the discovery and commercialization of novel pharmaceutical, vaccine and diagnostic products. In order for a product to be commercialized based on our research, it will be necessary for our alliance partner to conduct preclinical tests and clinical trials, obtain regulatory clearances, manufacture, sell, and distribute the product. Accordingly, we do not expect to receive royalties based upon product revenues for many years, if at all. We expect the majority of our revenue in the future to be derived through the sale of FACTIVE tablets and Testim.

We have incurred significant operating losses since our inception. As of March 31, 2005, we had an accumulated deficit of approximately $276.7 million. We expect to incur additional operating losses over the next several years due to the implementation of manufacturing, distribution, marketing and sales capabilities, as well as continued research and development efforts, preclinical testing and clinical trials.

Commercialization of FACTIVE

During the second half of 2004, we built a sales and marketing force in order to permit the launch of FACTIVE tablets in September of 2004. We began selling FACTIVE tablets in September 2004. During the quarter ended March 31, 2005, we completed the expansion of our sales and marketing team by hiring an additional 150 sales representatives in order to support a national sales force for FACTIVE.

Our ability to successfully commercialize FACTIVE tablets is subject to a number of risks, including the ability of our manufacturing partners to timely produce the needed quantities of the drug in compliance with regulations and competition in the marketplace from competing anti-infective products. If we are unable to successfully commercialize FACTIVE tablets, our operations, financial position and liquidity would be negatively affected to a significant degree.

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Co-Promotion of Testim

On April 11, 2005, we entered into a co-promotion agreement (the Agreement) with Auxilium Pharmaceuticals, Inc. (Auxilium) under which we and Auxilium will co-promote Auxilium s marketed product, Testim in the U.S. Testim is a proprietary, topical 1% testosterone gel indicated for the treatment of hypogonadism. We will have the exclusive right to promote Testim jointly with Auxilium to primary care physicians by using our 250-person sales force. We are obligated to commence co-promotion of Testim by May 9, 2005. 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 for each extension have been met by the Company. If these milestones are met and we do not elect to terminate the Agreement, the first extension period will commence on January 1, 2007 and end on December 31, 2008 and the second extension period will commence January 1, 2009 and end on April 30, 2011.

Both organizations will 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. primary care physician market. We are obligated to share Testim promotional expenses to this audience 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 under the Agreement.

The Agreement can be terminated by either party upon the occurrence of certain termination events. Auxilium may be obligated to make termination payments in certain instances. Also, we have been granted the exclusive option to co-promote any future product candidate of Auxilium s that treats hypogonadism and contains testosterone as the active ingredient.

Major Research and Development Projects

FACTIVE (gemifloxacin mesylate) Tablets

Our ongoing clinical trials and other development activities for the FACTIVE product totaled approximately $4,743,000 and $16,000 for the three-month periods ended March 31, 2005 and March 27, 2004, respectively. Development activity and associated expense for this product did not commence until the first quarter of 2004 following our acquisition of an exclusive license for the product.

In October 2002, Genesoft, now a subsidiary of ours, entered into a license and option agreement with LG Life Sciences to develop and commercialize gemifloxacin, a novel flouroquinolone 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. This agreement has subsequently been 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 expires in 2019. The product was approved for sale in the United States in April 2003 for the treatment of acute bacterial exacerbations 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 we are obligated to purchase from LG Life Sciences all of the Company s anticipated commercial requirements for FACTIVE bulk drug. LG Life Sciences is expected to supply the FACTIVE bulk drug substance from its manufacturing facility in South Korea. We have initiated a technology transfer process with Patheon Inc. including a CBE30

submission in April 2005, for the manufacture of finished products, to replace the previous fill and finish provider, SB Pharmco. We estimate that Patheon will obtain the necessary FDA qualifications to be the fill and finish provider of FACTIVE tablets during the first half of 2005. We expect that the quantities of FACTIVE tablets currently on hand, in combination with the quantities to be delivered from SB Pharmco, pursuant to pending purchase orders, will provide us with sufficient inventory until Patheon can be qualified. Assuming success on ongoing testing on the validation batches of FACTIVE tablets prepared by Patheon, these validation batches and additional inventory of tablets at Patheon are expected to be available for commercial use during the second quarter of 2005.

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. 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 for 2008 and periods commencing thereafter, in which case our 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.

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Under this license agreement, we were required to pay LG Life Sciences $8 million upon the completion of the merger with Genesoft. We are obligated to pay a royalty on sales of FACTIVE in the U.S. and the territories covered by the license in Europe. The royalty is fixed at a nominal rate during the first two years of commercial sales and increases thereafter. 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.

On March 31, 2005, we amended our license and option agreement with LG Life Sciences which included a reduction of future royalties payable to LG Life Sciences at certain FACTIVE revenue levels in territories covered by the agreement. As part of the modified agreement, we made a one time payment of $2 million to LG Life Sciences which was recorded to general and administrative expense in the three month period end March 31, 2005. In addition, the modified agreement requires additional milestone payments of up to $30 million upon obtainment of additional regulatory approvals and certain sales thresholds.

As a post-marketing study commitment, the FDA has required 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 will include 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 safety. This Phase IV trial commenced during the fall of 2004 and is scheduled to be completed within three years.

We are also seeking to expand the commercial opportunities for FACTIVE through additional development and clinical study plans for the product. As part of the FACTIVE development program, several studies in the acute bacterial sinusitis, or ABS, field were completed. We are in the process of discussing with the FDA activities related to an anticipated filing of a NDA for this indication during 2005. Our ability to achieve this goal, however, is subject to a number of risks, including safety risks related to the drug, such as rash, our ability to hire qualified clinical development and regulatory personnel and the possibility that the FDA may find that our clinical data fail to establish that the drug is effective or safe to treat this indication. As a result of these many risks and uncertainties, we can not predict when material cash inflows from our ABS program will commence, if ever. If we fail to meet our goal of filing the NDA by 2005 our market for FACTIVE will be restricted and this would have a negative impact on our operations, financial position and liquidity.

We have completed enrollment in 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. In addition, we have an intravenous formulation of gemifloxacin in development. Due to the risks and uncertainties inherent in clinical trials, we cannot predict if these efforts will be successful or when material cash flows from these programs will commence.

Ramoplanin

Our ongoing clinical trials and other development activities for Ramoplanin have constituted 7% and 83% of total research and development expenditures for three-month periods ended March 31, 2005 and March 27, 2004, respectively. Expenses for Ramoplanin have comprised 40% of the total research and development expense since inception of the project.

In October 2001, we acquired an exclusive license in the United States and Canada for a novel antibiotic, Ramoplanin, from Vicuron Pharmaceuticals Inc. (Vicuron). We have assumed responsibility for development of Ramoplanin in the United States. Our license agreement with Vicuron provides us with exclusive rights to develop and market oral Ramoplanin in the United States and Canada. Vicuron will retain all other rights to market and sell Ramoplanin. In addition, we are obligated to purchase bulk material from Vicuron, fund the completion of clinical

trials and pay a royalty on product sales. Upon commercialization the combined total of the bulk product purchases and royalties is expected to be approximately 26% of our net product sales.

On August 10, 2004, the Company announced preliminary results of its Phase II trial of Ramoplanin for the treatment of CDAD. We have submitted a special protocol assessment (SPA) to the FDA for the Phase III program of Ramoplanin for CDAD. These Phase II results are being discussed with the FDA as part of our SPA submission. Pending a successful outcome of these discussions and successful timetable discussions with our partner, Vicuron, the program would be ready to initiate Phase III testing.

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The successful commercialization of Ramoplanin is subject to many risks and uncertainties, including delays in the progress of our clinical trials, and increased cost, due to the pace of enrollment of patients in the trials, our inability to obtain product approval due to negative, inconclusive or insufficient clinical data and our inability to successfully market our product due to competition from other competing drugs. On November 8, 2004, we received a letter from Vicuron indicating that it intends to seek to terminate the License and Supply Agreement between Vicuron and Oscient and reacquire rights to Ramoplanin. In the letter, Vicuron claims that it will have a right to terminate the agreement based on the fact that an NDA with respect to Ramoplanin is not expected to be filed with the FDA prior to the date originally specified in the agreement. We believe the letter contradicts an amendment to the agreement entered into in October of 2002 (filed as exhibit 10.64 to our Annual Report on Form 10-K filed with the SEC on March 31, 2003), and we have addressed this issue with Vicuron. Pursuant to the terms of the amended agreement, we are in discussions with Vicuron to develop a timetable for the completion of development and outside date for the NDA submission. There is no assurance we will be able to agree upon such a date, that Vicuron will not renew its attempt to terminate the agreement again in the future or that we will prevail in any potential dispute with Vicuron. As a result of these many risks and uncertainties, we can not predict when material cash inflows from our Ramoplanin project will commence, if ever. A failure to obtain a marketing approval for Ramoplanin and to successfully commercialize the drug would have a significant negative impact on our operations, financial position and liquidity.

Internally Funded Research Program

As part of our strategic decision to concentrate on development and commercialization of our own products, we adopted a plan in 2003 to substantially reduce our research effort in internally funded early-stage target discovery programs. Under this plan, we eliminated 44 full-time positions and recorded a restructuring charge of approximately $5.4 million through September 25, 2004. This charge consisted of a reduction in work force and includes associated severance costs, outplacement services and a non-cash charge for the acceleration of vesting of previously granted stock options, as well as impairment charges related to the value of laboratory and computer equipment no longer used in operations.

As a combined category, these research efforts represented 0% and 4% of total research and development expenses for the three-month periods ended March 31, 2005 and March 27, 2004, respectively. These efforts comprised 41% of the total research and development expense from January 1, 1995 through March 31, 2005.

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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 1 in the Notes to the Consolidated Financial Statements of this Annual Report on Form 10-K. Our preparation of this Report requires us to make estimates and assumptions that affect the reported amount of assets and liabilities, disclosure of contingent assets and liabilities at the date of our consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Our critical accounting policies include the following:

Revenue Recognition

Our principal source of revenue is the sale of FACTIVE, which began shipping in the third quarter of 2004. Other sources of revenue include biopharmaceutical alliances and royalties from the divested genomic services business. In future periods, we expect its revenues derived from biopharmaceutical alliances will continue to decrease and product revenues will continue to increase based on anticipated increased volume in prescriptions of FACTIVE tablets and Testim, due to the Company entering into a co-promotion agreement with Auxilium Pharmaceuticals, Inc. on April 11, 2005.

Inventory

Inventory is stated at the lower of cost or market with cost determined under the first-in, first-out (FIFO) method. As of March 31, 2005, inventory consists of FACTIVE raw material in powder form and work-in-process and FACTIVE finished tablets to be used for sample and commercial sale. On a quarterly basis, we analyze its inventory levels, and write down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory that is in excess of expected requirements to cost of product revenues. Expired inventory will be disposed of and the related costs will be written off. At March 31, 2005, there is approximately $ 6,721,000 of inventory that relates to validation lots and active pharmaceutical ingredients that are not yet saleable until the FDA acceptance of our manufacturing site at Patheon. This approval is expected in the second quarter of 2005.

Product Sales/Deferred Revenue

We follow the provisions of Staff Accounting Bulletin No. 104, Revenue Recognition (a replacement of SAB 101) and recognizes revenue from product sales upon delivery of product to wholesalers, when persuasive evidence of an arrangement exists, the fee is fixed or determinable, title to product and associated risk of loss has passed to the wholesaler and collectability of the related receivable is reasonably assured. All revenues from product sales are recorded net of applicable allowances for sales returns, rebates, chargebacks, 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, cost of FACTIVE associated with amounts recorded as deferred revenue are recorded in inventory until such time as risk of loss has passed.

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Sales Rebates, Discounts and Incentives

Our product sales are subject to various rebates, discounts and incentives that are customary in the pharmaceutical industry. During the third quarter of 2004, we offered certain product stocking incentives to a number of pharmacy customers. These incentives included units with limited guaranteed sales provisions. As a result of these provisions, title and risk of loss of these units has not passed to the customer. Accordingly, we have deferred all revenue related to these units until such time as the unit is provided to a patient with a prescription. As of March 31, 2005, we have recorded deferred revenue of approximately $912,000 related to these units.

During the fourth quarter of 2004, we initiated a sample card program whereby we offered an incentive to patients in the form of free full-course sample card. We have accounted for this program in accordance with Emerging Issues Task Force Issue No. 01-09, *Accounting for Consideration Given by a Vendor to a Customer* (EITF 01-09). As of March 31, 2005, we did not have sufficient history with these types of incentive programs in order to develop a reasonable and reliable estimate of the amount of reimbursement claims that we expect to realize. As a result, we have recorded the maximum liability (100% redemption) for reimbursement claims related to sample cards distributed as of March 31, 2005 which resulted in a reduction of revenues. We will adjust the liability upon completion of the program, which will result in additional product revenue being recorded at that time. The sample card program is expected to be completed in the second half of 2005 and we may be able to consider the actual redemption rate in estimating the liability for similar programs in the future.

During the first quarter of 2005, we initiated a voucher rebate program whereby it offered a rebate to patients who received a FACTIVE prescription. We have accounted for this program in accordance with EITF No. 01-09. As of March 31, 2005, we were able to develop a reasonable estimate of the liability for this program based upon historical redemption rates for completed programs by third parties. As of March 31, 2005, the reserve balance associated with the voucher rebate program was approximately $101,000. The program is expected to continue through at least the first half of 2005.

Our product sales are made to pharmaceutical wholesalers for further distribution through pharmacies to the ultimate consumers of our product. All revenues from product sales are recorded net of applicable allowances for returns, wholesaler chargebacks, cash discounts, and administrative fees. We estimate wholesaler chargebacks, cash discounts, administrative fees and other rebates by considering the following factors: current contract prices and terms, estimated customer and wholesaler inventory levels and current average chargeback rates. Our process to estimate product returns includes the remaining shelf life and the product life cycle stage. We estimate product return allowances based on historical information for similar or competing products in the same distribution channel. We obtain and evaluate product return data from distributors and, based on this evaluation, estimate return rates. The reserves are reviewed at each reporting period and adjusted to reflect data available at that time. To the extent our estimates of contractual allowances, rebates and sales returns are different from actuals, we adjust the reserve which impacts the amount of product sales revenue recognized in the period of the adjustment. We have not received any significant returns through March 31, 2005.

Clinical Trial Expense Accrual

Our clinical development trials related to Ramoplanin and FACTIVE are primarily performed by outside parties. It is not unusual at the end of each accounting period for us to 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 quarter ended March 31, 2005, we adjusted our accrual for clinical trial expenditures to reflect our most current estimate of liabilities outstanding to outside parties, resulting in a favorable change in estimate in the accrual for clinical development expenditures. However, readers should be cautioned that 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.

Results of Operations

Three Month Period Ended March 31, 2005 and March 27, 2004

Revenues

Total revenues increased 138% to approximately $3,945,000 for the three month period ended March 31, 2005 from approximately $1,661,000 for the three month period ended March 27, 2004.

Product sales increased to approximately $3,912,000 for the three month period ended March 31, 2005 from $0 for the three month period ended March 27, 2004 due to the launch of commercial sale of FACTIVE tablets in September 2004.

Biopharmaceutical revenues decreased 98% to approximately $34,000 for the three month period ended March 31, 2005 from approximately $1,661,000 for the three month period ended March 27, 2004, primarily due to the reduction of revenues from alliances as a result of the conclusion of research agreements.

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There will be a shift in the revenue mix in 2005. We expect our revenues derived from both our biopharmaceutical alliance and genomics services will become zero in comparison to prior years and an increase in product revenues based on the sale of FACTIVE tablets and Testim.

Costs and Expenses

Total costs and expenses increased 57% to approximately $33,207,000 for the three month period ended March 31, 2005 from approximately $21,187,000 for the three month ended March 27, 2004.

Cost of product sales increased to approximately $2,066,000 for the three month period ended March 31, 2005 from $0 for the three month period ended March 27, 2004 due to the launch of FACTIVE tablets in September 2004. Included in the cost of product sales is approximately $1,192,000 of amortization of intangibles assets associated with FACTIVE.

Research and development expenses include internal research and development expenses, research funded pursuant to arrangements with our government grants, 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 slightly to approximately $5,168,000 for the three month period ended March 31, 2005 from approximately $5,195,000 for the three month period ended March 27, 2004. While the expenses are relatively consistent, it reflects a shift in development focus from Ramoplanin (termination of the VRE Phase III clinical program) to FACTIVE (primarily the 5-day CAP study).

Selling, general and administrative expenses increased significantly to approximately $25,025,000 for the three month period ended March 31, 2005 from $3,625,000 for the three month period ended March 27, 2004. The increase in selling, general and administrative expenses is due to increased sales and marketing personnel and related costs of approximately $9,718,000, increased other selling and marketing costs of approximately $3,959,000 to support the launch of FACTIVE, increased advertising and promotional costs of approximately $5,266,000, increased general and administrative personnel, hiring and consulting costs of approximately $203,000 and increased legal and patent costs of approximately $2,254,000. Selling, general and administrative expenses are expected to increase at a slower pace from previous quarters as the Company completed the expansion of its primary care sales force with the hiring of 150 new sales representatives in order to expand our commercialization efforts related to FACTIVE. The anticipated increase in selling and marketing is due to the co-promotion agreement signed with Auxilium Pharmaceuticals, Inc. on April 11, 2005.

Stock-based compensation increased 68% to approximately $949,000 for the three month period ended March 31, 2005 from approximately $565,000 for the three month period ended March 27, 2004. The increase was due to higher amortization of deferred compensation resulting from stock options being issued, and then the expense being accelerated due to terminations in connection with the merger completed with GeneSoft Pharmaceuticals in February 2004.

Other Income and Expense

Interest income increased significantly to approximately $870,000 for the three month period ended March 31, 2005 from approximately $192,000 for the three month period ended March 27, 2004 reflecting higher cash balances due to the proceeds of the public offering of our common stock received in the first quarter of 2004 and the convertible debt proceeds received in the second quarter of 2004 as well as higher

interest rate yields from investments.

Interest expense increased significantly to approximately $2,044,000 for the three month period ended March 31, 2005 from approximately $296,000 for the three month period ended March 27, 2004, primarily due to interest expense of approximately $1,337,000 related to the issuance of $153 million of senior convertible notes in the second quarter of 2004, $290,000 related to the issuance of $22 million of convertible notes in connection with the Genesoft merger, $204,000 related to amortization of deferred financing costs along with $202,000 related to non-cash interest expense related to the facility lease liability which was recorded during the quarter ended March 27, 2004.

We recorded gain on the sale of fixed assets of approximately $38,000 and $51,000 for the three month periods ended March 31 2005 and March 27, 2004, respectively, primarily due to the sale of laboratory and computer equipment, which were no longer used in operations.

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

For the three month period ended March 31, 2005, we recorded other income of approximately $40,000, primarily due to miscellaneous license fees related to genomic based software sold in previous periods.

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Liquidity and Capital Resources

Our primary sources of cash have been payments received from product discovery alliances, proceeds from the sale of debt and equity securities, subscription fees, government grants, borrowings under equipment lending facilities and capital leases.

As of March 31, 2005, we had cash, cash equivalents and short-term marketable securities of approximately $127,909,000.

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 $6.64 per share. We may not redeem the notes at our election 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 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.

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 June 4, 2003, we entered into an Amendment, Redemption and Exchange Agreement with two institutional investors providing for (a) the redemption in cash of a portion of the 6% Convertible Notes due December 31, 2004, (b) the conversion of the remaining portion of the convertible notes into our common stock and the (c) issuance to the investors of new warrants in exchange for warrants previously held by the investors. Under the terms of the agreement, we redeemed an aggregate of $10,000,000 in principal amount of the convertible notes for a cash payment of $10,000,000 to the investors, and the related accrued and unpaid interest on such principal amount of the convertible notes for a cash payment of an aggregate of $254,795 to the investors. The conversion price of the remaining $5,000,000 in principal amount of the convertible notes was amended to equal $2.5686 per share and the investors converted the remaining amount of the convertible notes, plus related accrued and unpaid interest, into 1,996,184 shares of our common stock. We also issued new warrants in exchange for the warrants that were previously issued to the investors. The new warrants have a term of five years from the issuance date, are immediately exercisable and allow the investors to purchase in the aggregate up to 535,806 shares of our common stock at an exercise price of $3.37 per share.

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 was 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 $6.6418 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 them by Genesoft.

Our operating activities used cash of approximately $30,392,000 and $4,931,000 for the three month periods ended March 31, 2005 and March 27, 2004, respectively. Cash used in our operating activities for three month period ended March 31, 2005 was primarily a result of our net loss of approximately $27,836,000, 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 prepaid expenses to our contracted sales force 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 $702,000 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 depreciation and amortization expenses of approximately $2,279,000 as well as non-cash interest expenses of approximately $405,000.

Our investing activities provided cash of approximately $46,444,000 for the three month period ended and March 31, 2005 and used cash of approximately $55,903,000 for the three month period ended March 27, 2004. 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 and proceeds from sales of property and equipment of approximately $135,000. Cash provided from investing activities were partially offset by purchases of property and equipment of approximately $338,000 and increase in restricted cash of approximately $32,000. Cash used by our investing activities for the three month period ended March 27, 2004 was primarily related to $14,989,000 of merger costs, purchases of marketable securities of $45,336,000, and net purchases property and equipment of $35,000. These uses of cash were partially offset by proceeds from maturities of marketable securities of approximately $2,832,000 and decreases in other assets and intangible assets of approximately $1,626,000.

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Capital expenditures totaled approximately $338,000 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 and $49,000 for the three month period ended March 27, 2004 primarily consisting of purchases of computer and related equipment.

Our financing activities used cash of approximately $1,126,000 for the three month period ended March 31, 2005, primarily due to the issuance of a note receivable of $1,387,000 related to a deposit required in order to lease vehicles for the sale representatives and payments of long-term obligations of $292,000. These uses were offset by 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. Our financing activities provided cash of approximately $81,523,000 for the three month period ended March 27, 2004, primarily due to net proceeds from issuance of stock through private placement of $80,864,000, and proceeds from exercise of stock options of $859,000 and proceeds from issuance of shares under the employee stock purchase plan of approximately $136,000. These proceeds were partially offset by payments of long-term obligation of $337,000.

At December 31, 2004, we had net operating loss carryforwards of approximately $289,440,000 and $225,053,000, available to reduce federal and state taxable income respectively, if any. In addition, we also had tax credit carryforwards of approximately $18,991,000 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 of our common stock over a three-year period in excess of 50%. Additionally, certain of our losses have begun to expire due to time, not limitations.

We believe that, under our current rate of investment in development programs, that our existing capital resources are adequate for at least through the end of 2006. 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 as we have built a sales and marketing organization in order to commercialize FACTIVE tablets, expand the medical/development organization to support additional FACTIVE development and commercialization, continue support for the development of Ramoplanin and build the infrastructure necessary to support these expansions. We would expect growth, particularly in the sales and marketing areas, to continue to increase, however at a slower pace during 2005 as we begin to promote the sale of Testim and expand FACTIVE during the second half of 2005.

Contractual Obligations

Our major outstanding contractual obligations relate to our convertible promissory note and our facility leases. As of March 31, 2005, the following table summarizes our significant contractual obligations and the effect such obligations are expected to have on our liquidity and cash flow in future periods (in thousands):

	2005	2006	2007	2008	2009	Thereafter	Total
Operating leases	$ 4,380	$ 5,918	$ 5,098	$ 5,424	$ 5,613	$ 7,829	$ 34,262
Sublease contracted income	(2,891)	(3,719)	(1,135)				(7,745)
Current sublease forecasts (a)				(1,579)	(1,575)	(1,899)	(5,053)
	1,489	2,199	3,963	3,845	4,038	5,930	21,464

Convertible promissory notes (b)	5,346	5,346	5,346	5,346	33,904	160,769	216,057
Total forecasted contractual obligations	$ 6,835	$ 7,545	$ 9,309	$ 9,191	$ 37,942	$ 166,699	$ 237,521

(a) The current market reflects lower demand and cost for space, as well as shorter term leases.

(b) Upon the closing of the Genesoft merger, we exchanged approximately $22 million of Company convertible promissory notes for a like principal amount of Genesoft promissory notes. The convertible promissory notes bear an interest rate of 5% compounded semi-annually and have a maturity date of five years from the closing date. The convertible promissory notes are convertible into shares of our common stock at the holder s election at any time at a price per share equal to $6.6418, subject to subsequent adjustment. In addition, following the one year anniversary of the closing of the merger, we will 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. The convertible promissory notes payable of $28.6 million at maturity date includes $6.2 million of accrued interest payable.

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In the quarter ended June 26, 2004, the Company issued $152,750,000 in principal amount of our 3.5% senior convertible promissory notes due April 2011. These notes are convertible into our common stock at the option of the holders at a conversion price of $6.64 per share. The Company may not redeem the notes at its election 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.

FACTORS AFFECTING FUTURE OPERATING RESULTS

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 $93,271,000 for the fiscal year ended December 31, 2004 and as of March 31, 2005, we had an accumulated deficit of approximately $276,672,000. We had a net loss of approximately $29,789,000 for the fiscal year ended December 31, 2003, and, as of December 31, 2003, we had an accumulated deficit of approximately $155,564,000. For the fiscal year ended December 31, 2002, we had a net loss of approximately $34,017,000, and for the fiscal year ended December 31, 2001, we had a net loss of approximately $10,090,000. The losses have resulted primarily from costs incurred in research and development, including our clinical trials, and from general and administrative costs associated with our operations, prior to 2004, and product sales of FACTIVE tablets. These costs have exceeded our revenues which to date have been generated principally from collaborations, government grants and sequencing services.

We anticipate that we will incur additional losses in the current year and in future years and cannot predict when, if ever, we will achieve profitability. These losses are expected to continue and potentially increase as we continue significant levels of expenditures, principally in the sales and marketing area as we seek to grow sales of FACTIVE tablets and begin co-promotion of Testim and in research and development in connection with clinical trials and formulation activities to support the existing labeling of FACTIVE tablets and potentially the expanded FACTIVE labeling claims. 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.

Our business will be very dependent on the commercial success of FACTIVE and Testim.

FACTIVE tablets and Testim are currently our only commercial products and we expect 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 has been approved by the FDA for the treatment of 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 hypogonadism, in the case of Testim. The commercial success of Testim is also dependant, 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.

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 postmarketing study commitment, that we conduct a prospective, randomized study comparing the FACTIVE tablet (5,000 patients) to an active comparator (2,500 patients) in patients with CAP or AECB. This study will include 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 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 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 will furnish periodic reports to the FDA 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 periodic reports we are required to provide to the FDA, as well as other safety information arising out of the marketing of the product, could restrict our ability to commercialize FACTIVE tablets.

We may need to raise additional funds in the future.

We believe our existing funds and anticipated cash flows from operations would be sufficient to support our current plans through the end of 2006. We may need to 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 financings or agreements with customers. 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

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programs over that period. 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 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 considering the launch of FACTIVE occurred in September of 2004 and co-promotion of Testim is scheduled to begin in May of 2005. The continued development of these marketing and sales capabilities will require significant expenditures, management resources and time. Failure to successfully establish sufficient sales and marketing capability in a timely and regulatory compliant manner or to find suitable sales and marketing partners may adversely affect our business and results of operations.

If testosterone replacement therapies are perceived to create or 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 potential health risks associated with testosterone replacement therapy (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.

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 the FDA s current Good Manufacturing Practices. Under our agreement with LG Life Sciences they manufacture bulk quantities of the active pharmaceutical ingredient of FACTIVE. The Co-Promotion Agreement for Testim provides that Auxilium is responsible for the manufacture and distribution of Testim. Testim 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.

We are seeking to qualify Patheon, Inc. as a manufacturer to provide finished FACTIVE tablets, replacing SB Pharmaco. We estimate that Patheon will obtain the necessary FDA qualifications to be the fill and finish provider during the first half of 2005. The Company expects that the quantities of FACTIVE tablets currently on hand, in combination with the quantities to be delivered from SB Pharmco (under its current obligations), will provide sufficient inventory until Patheon can be qualified. However, if there is significant delay in the qualification of Patheon, we could have insufficient inventory of FACTIVE tablets to meet demand which could adversely affect our business and results of operations. In addition, we cannot assure you that SB Pharmco will be able to avoid batch failures or production delays for its outstanding commitments.

Auxilum s contract with DPT Laboratories to manufacture Testim expires on December 31, 2005. Although Auxilium is currently in the process of qualifying a back-up supplier to manufacture Testim, there is currently no alternative manufacturer of Testim. If there is significant delay in qualifying this back-up supplier, there could be future supply shortages of Testim. Auxilium also relies on third party suppliers for their supply of testosterone and pentadecalactone, or CPD, two key ingredients of Testim. 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.

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We cannot be certain that LG Life Sciences, DPT Laboratories, Patheon, Vicuron 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 product is LG Life Sciences facility in South Korea, and upon FDA qualification, Patheon will be our only source of finished FACTIVE tablets. DPT Laboratories is currently the only qualified manufacturer of Testim. If these facilities are damaged or otherwise unavailable, we would incur substantial costs and delay in the commercialization of our products. If we are forced to find an alternative source for Ramoplanin or other product candidates, we could also incur substantial costs and delays in the further commercialization of such products. We may not be able to enter into alternative supply arrangements at commercially acceptable rates, if at all. Also, if we change the source or location of supply or modify the manufacturing process, regulatory authorities will require us to demonstrate that the product produced by the new source or from the modified process is equivalent to the product used in any clinical trials that we had conducted.

Moreover, while we may choose to manufacture products in the future, we have no experience in the manufacture of pharmaceutical products for clinical trials or commercial purposes. If we decide to manufacture products, it would be subject to the regulatory requirements described above. In addition, we would require substantial additional capital and would be subject to delays or difficulties encountered in manufacturing pharmaceutical products. No matter who manufactures the products, we will be subject to continuing obligations regarding the submission of safety reports and other post-market information.

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. In June, we entered into an exclusive agreement 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.

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.

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 treatment of community-acquired pneumonia of mild to moderate severity and acute bacterial exacerbations of chronic bronchitis. One of our objectives is to expand the indications for which FACTIVE is approved for marketing by the FDA, including for the indication of acute bacterial sinusitis. While we believe the necessary clinical trials for acute bacterial sinusitis have been completed, we are gathering additional data based on the use of FACTIVE following commercial launch to supplement an NDA filing for acute bacterial sinusitis (ABS). We cannot be certain how many additional data will be required or whether we will be required to conduct additional clinical trials in order to market FACTIVE for this indication. In order to market FACTIVE for other indications, we will 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.

Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing FACTIVE abroad.

In order to market FACTIVE in the European Union 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. 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.

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

Our exclusive rights to market FACTIVE in Europe are limited to France, Germany, the United Kingdom, Luxembourg, Ireland, Italy, Spain, Portugal, Belgium, the Netherlands, Austria, Greece, Sweden, Denmark, Finland, Norway, Iceland, Switzerland, Andorra, Monaco, San Marino and Vatican City. These countries included all of the members of the European Union on the date of the original agreement to license FACTIVE. However, in 2004, a number of additional European countries in which we do not have rights to market FACTIVE were admitted as members of the European Union. If LG Life Sciences were to sell FACTIVE or license a third party to sell FACTIVE in such countries, our ability to maintain our projected profit margins based on sales in the territories covered by the LG Life Sciences license agreement may be adversely affected because customers in our territory may purchase FACTIVE from neighboring countries in the European Union and our ability to prohibit such purchases may be limited under European Union antitrust restrictions.

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Failure to secure distribution partners in foreign jurisdictions will prevent us from marketing FACTIVE abroad.

We intend to market FACTIVE through distribution partners in most, if not all, of the international markets for which we have a license to market the product. This will include the European Union, Canada and Mexico. We may not be able to secure distribution partners at all, or those that we do secure may not be successful 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.

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 manufacture and support the development and commercialization of our products do not fulfill their obligations.

Our development and commercialization strategy entails entering into arrangements with corporate and academic collaborators, contract research organizations, distributors, third-party manufacturers, licensors, licensees and others to conduct development work, manage our clinical trials, manufacture our products 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.

We may not be able to maintain our existing arrangements with respect to the commercialization of our products 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, manufacturing and commercializing our products are not within our control. Furthermore, our interests may differ from those of third parties that manufacture or commercialize our products. Disagreements that may arise with these third parties could delay or lead to the termination of the development or commercialization of our product candidates, or result in litigation or arbitration, which would be time consuming and expensive.

If any third party that manufactures or 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.

Our lead product, FACTIVE tablets, is currently conducting a Phase IV post-approval clinical trial in compliance with FDA requirements pursuant to the product s approval and a Phase III clinical trial for a five-day course of therapy for the treatment of community-acquired pneumonia of mild to moderate severity. Additionally, clinical trials may be necessary to gain approval to market the product for the treatment of acute bacterial sinusitis. Additional clinical trials will be required to gain approval to market FACTIVE for other indications/formulations.

The Phase II trial for our lead product candidate, Ramoplanin, to assess the safety and efficacy to treat *Clostridium difficile*-associated diarrhea, or CDAD, was completed in 2004. Pending completion of discussions with the FDA regarding a Special Protocol Assessment submitted in late 2004 and completion of discussions with our partner, Vicuron, concerning timelines required to complete the Phase III program and submission to the FDA, the Phase III program will be ready for initiation. Prior clinical and preclinical trials for Ramoplanin were conducted by Vicuron and its licensees, from whom we acquired our license to develop Ramoplanin. We may not be able to complete these 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, including as a result of increased costs.

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.

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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 enrolled in our trials;
- compliance of patients and investigators with the protocol and applicable regulations;
- prior regulatory agency review and approval of our applications and procedures;
- analysis of data obtained from preclinical and clinical activities which are susceptible to varying interpretations, which interpretations could delay, limit or prevent regulatory approval;
- changes in the policies of regulatory authorities for drug approval during the period of product development; and
- the availability of skilled and experienced staff to conduct and monitor clinical studies, to accurately collect data and to prepare the appropriate regulatory applications.

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

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.

If regulatory approval of a drug is granted, such approval is likely to limit the indicated uses for which it may be marketed. Furthermore, even if a product gains regulatory approval, the product and the manufacturer of the product will be subject to continuing regulatory review, including the requirement to conduct post-approval clinical studies. We may be restricted or prohibited from marketing or manufacturing a product, even after obtaining product approval, if previously unknown problems with the product or its manufacture are subsequently discovered.

Our 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® (levofloxacin), a product of Ortho-McNeil Pharmaceutical, Inc., Tequin® (gatifloxacin), a product of Bristol-Myers Squibb Company, and Cipro® (ciprofloxacin) and Avelox® (moxifloxacin), both products of Bayer Corporation;

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

- Ketek, a ketolide from Aventis Pharmaceuticals; and

- penicillins such as Augmentin® (amoxicillin/clavulanate potassium), a product of GlaxoSmithKline.

Many generic antibiotics are also currently prescribed to treat these infections. Moreover, a number of the antibiotic products that are competitors of FACTIVE tablets will be going off patent at dates ranging from 2003 to 2015. As these competitors lose patent protection, 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 for the treatment of hypogonadism is AndroGel(R), marketed by Solvay Pharmaceuticals. AndroGel(R) was launched approximately three years before Testim and, according to IMS, has a much larger share of the testosterone gel market than Testim and also accounted for approximately 58% of total testosterone prescriptions for the quarter ended March 31, 2005. Testim also competes with other forms of testosterone replacement therapies such as oral treatments, patches, injectables and a buccal tablet. Generally, Testim is more expensive than patches and injectables. AndroDerm(R) is a transdermal testosterone patch marketed by Watson Pharmaceuticals. AndroDerm(R) is the leading patch product and accounted for approximately 12% of total testosterone prescriptions for the quarter ended March 31, 2005. Other new treatments are being sought for TRT which may compete with Testim, including a new class of drugs called Selective Androgen Receptor Modulators.

We are also aware of at least two companies, Watson and Par Pharmaceutical, that have filed abbreviated new drug applications, or ANDAs, with the FDA to be approved as generics of AndroGel(R). Solvay has filed patent infringement lawsuits against these two companies to block the approval and marketing of the generic products. On November 1, 2004, Par Pharmaceutical s partner, Paddock Laboratories, received tentative approval of its ANDA from the FDA, but cannot market its generic of AndroGel(R) until the Solvay action is resolved and until final approval is received from the FDA. The final approval of either or both of these ANDAs would result in increased competition for Testim at lower prices.

Ramoplanin is in clinical development for the treatment of *Clostridium difficile*-associated diarrhea (CDAD). We are aware of two products currently utilized in the marketplace Vancomin® (vancomycin), a product marketed by ViroPharma, and metronidazole, a generic product for treatment of this indication. We are also aware of at least four companies with products in development for the treatment of CDAD Genzyme in Phase III; Par Pharmaceuticals/Optimer Pharmaceuticals in Phase IIa; ImmuCell in Phase I/II; and Acambis in Phase I/II. It is also possible that other companies are developing competitive products for this indication. We are aware that Vicuron and Novartis Pharma are jointly developing PDF inhibitor agents that may compete with any PDF products developed by us.

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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, 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 will rely upon alliance partners from our previous Genomics-Based Research & Alliance Business as a means of developing and commercializing our products.

Our strategy for developing and commercializing therapeutic, vaccine and diagnostic products from our previous Genomics-Based Research and Alliance Business depends, in part, on strategic alliances and licensing arrangements with pharmaceutical and biotechnology partners. We currently have alliances with bioMerieux, Schering-Plough and Wyeth. Over the past several years, we have received a substantial portion of our revenue from these alliances. However, our research obligations under our strategic alliances have been fulfilled. As a result, any substantial additional revenues under these alliances will consist of milestone payments based on the achievement by the alliance partner of development milestones or royalties based on the sale of products arising from the alliance. The achievement of any of the development milestones and successful development of any products under these alliances are dependent on the alliance partners activities and are beyond our control. We cannot assure you that any milestones will be attained, that any products will be successfully developed by the alliance partners or that we will receive any substantial additional revenues under these alliances.

If our partners develop products using our discoveries, we will rely on these partners for product development, regulatory approval, manufacturing and marketing of those products before we can receive some of the milestone payments, royalties and other payments to which we may be entitled under the terms of some of its alliance agreements. Our agreements with our partners typically allow the partners significant discretion in electing whether to pursue any of these activities. We will not be able to control the amount and timing of resources our partners may devote to our programs or potential products. As a result, there can be no assurance that our partners will perform their obligations as expected.

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 and develop 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.

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, non-toxic and effective or approved by regulatory authorities. In addition, it is uncertain whether any approved products that we develop or acquire will be:

manufactured or produced economically;

successfully commercialized; or

widely accepted in the marketplace.

We 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; Nick Colangelo, Esq., Senior Vice President, Corporate Development and Operations; and Ton Bunt, M.D., Ph.D., Senior Vice President, Clinical Development and Medical Affairs. The term of each employment agreement continues until it is terminated by the officer or us. We do not currently maintain key person life insurance on any of our employees.

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

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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.

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 63 issued U.S. patents, approximately 84 pending U.S. patent applications, 113 issued foreign patents and approximately 198 pending foreign patent applications. These patents and patent applications primarily relate to (1) the field of human and pathogen genetics, (2) the chemical composition, use, and method of manufacturing FACTIVE, (3) metalloenzyme inhibitors, their uses, and their targets, and (4) DNA-Nanobinder(TM) compounds and their use as anti-infective therapeutics. 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-methyloxyiminopyrroplidin-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. 5,869,670 granted February 9, 1999, relating to 7-(4-aminomethyl-3-methyloxyiminopyrrolidin-1-yl)-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1,8-naphthyridine-3-carboxylic acid; licensed from LG Life Sciences; expiring June 15, 2015;

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

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

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

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

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

U.S. Patent No. 6,723,734 granted April 20, 2004, relating to the salt of naphythyridine 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.

Under our license agreement with LG Life Sciences, we obtained an exclusive license to develop and market gemifloxacin in certain territories. This license covers 16 issued U.S. patents and a broad portfolio of corresponding foreign patents and pending patent applications. These patents include claims that relate to the chemical composition of FACTIVE, methods of manufacturing and its use for the prophylaxis and treatment of bacterial infections. We have filed a patent term extension application covering the regulatory review process for one of the principal patents, U.S. Patent 5,776,944, expiring 2015. If granted, this extension would extend the exclusivity period through 2017. The U.S. patents are currently set to expire at various dates, ranging from 2015 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.

LG Life Sciences, as owner of U.S. Patent Nos. 5,776,944 and 5,962,468, submitted requests for reexamination to the U.S. Patent & Trademark Office, or PTO, in order to place additional references into the record of each patent. Both requests were granted by the PTO. Patent 944 and 468 have been reexamined with relatively minor modifications to the claims and confirmed patentable over the submitted references.

The patents that we license to Ramoplanin under our agreement with Vicuron 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 year data exclusivity provisions under the Hatch-Waxman Act.

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 they 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;

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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; and

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 is not covered by composition of matter patents. Testosterone, the active ingredient in Testim, 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 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. Moreover, patent prosecution, maintenance and enforcement of the Bentley patent portfolio as it relates to Testim 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 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.

We will bear substantial responsibilities under our license agreements for FACTIVE and Ramoplanin and our co-promotion agreement for Testim, and there can be no assurance that we will successfully fulfill our responsibilities.

In connection with the merger, we have assumed Genesoft s 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; provided, that, unless the Company s annual sales of FACTIVE reach a certain target level, LG Life Sciences has the right to co-promote the product on terms to be negotiated in our territory for 2008 and periods commencing thereafter, in which case our royalty obligations to LG Life Sciences would cease. 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 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.

On April 11, 2005, we entered into an agreement with Auxilium granting us the exclusive right to co-promote Testim 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 the Company 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.

Under our agreement with Vicuron, we have obtained an exclusive license to develop and market oral Ramoplanin in the United States and Canada. Under this agreement, we are responsible, at our expense, for the clinical and non-clinical development of Ramoplanin in our field, the prevention and treatment of human disease, in the United States and Canada, including the conduct of clinical trials and the filing of drug approval applications with the FDA and other applicable regulatory authorities. We are obligated under the agreement to work diligently to develop Ramoplanin and if we do not file an NDA for Ramoplanin by a date to be agreed upon by us and Vicuron, Vicuron would have the right to terminate our license to Ramoplanin. On November 8, 2004, we received a letter from Vicuron Pharmaceuticals Inc. indicating that it intends to seek to terminate the License and Supply Agreement between Vicuron and Oscient and reacquire rights to Ramoplanin. In its letter, Vicuron claims that it will have a right to terminate the agreement based on the fact that an NDA with respect to Ramoplanin is not expected to be filed with the FDA prior to the date originally specified in the agreement. We believe this letter contradicts an amendment to the agreement entered into in October of 2002 (filed as exhibit 10.64 to our Annual Report on Form 10-K filed with the SEC on March 31, 2003), and we have addressed this issue with Vicuron. Pursuant to the terms of the amended agreement, we are in discussions with Vicuron to develop a timetable for the completion of development and outside date for the NDA submission. There is no assurance we will be able to agree upon such a date, that Vicuron will not renew its attempt to terminate the agreement again in the future or that we will prevail in any potential dispute with Vicuron.

Vicuron is responsible for providing us with all information in its possession relating to Ramoplanin in our licensed field, for cooperating with us in obtaining regulatory approvals of Ramoplanin and for using diligent efforts to provide us with bulk Ramoplanin sufficient to carry out our clinical development activities. We believe that we are currently in compliance with our obligations under the License and Supply Agreement, 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.

Under our agreement with Vicuron, Vicuron has the obligation to prosecute patents relating to Ramoplanin that are made by Vicuron personnel or conceived jointly by our personnel and Vicuron s personnel. We have the obligation to prosecute patents

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relating to Ramoplanin that are made solely by our personnel. We have the right to control any suits brought by a third party alleging that the manufacture, use or sale of Ramoplanin in our licensed field in the United States or Canada infringes upon our rights. We will bear the costs of any such actions, which could be substantial; provided that if we are obligated to pay any royalties or other payments to a third party to sell Ramoplanin as a result of this litigation, including any settlement reached with Vicuron s consent, Vicuron is obligated to pay that expense. We also have the primary right to pursue actions for infringement of any patent licensed from Vicuron within the United States and Canada within our licensed field. Vicuron has the primary right to pursue actions for infringement of any patents that it licenses to us outside of our licensed field within the United States and Canada and for all purposes outside of the United States and Canada. If the party with the primary right to pursue the infringement action elects not to pursue it, the other party generally has the right to pursue it. The costs of any infringement actions are first paid out of any damages recovered and are then allocated to the parties depending upon their interest in the suit. The costs of pursuing any such action could substantially diminish our resources.

We as well as our partner 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 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 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. 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 seeing regulatory approval for our products or product candidates. Such changes may increase our costs and adversely effect our operations.

Testim 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. For example, all regular Schedule III drug prescriptions must be signed by a physician and may not be refilled. 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.

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 introduction and marketing of our product candidates. For some scheduled substances, the FDA may require us or our partners to develop a comprehensive risk management program to reduce the inappropriate use of our products and product candidates, including the manner in which they are marketed and sold, so as to reduce the risk of improper patient selection and diversion or abuse of the product. Developing such a program in consultation with the FDA may be a time-consuming process and could delay approval of any of our product candidates. Such a program or delays of any approval from the FDA could increase our product development costs and may allow our competitors additional time to develop or market competing products.

Additionally, 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;
- 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;
- 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 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.

Our proprietary position may depend on our ability to protect trade secrets.

We rely upon 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 trade secrets will not otherwise become known or be independently discovered by competitors.

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.

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.

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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 December 31, 2004, after giving effect to the issuance and sale of the convertible notes during the second quarter of 2004, we had approximately $176 million of indebtedness outstanding (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, 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, Ramoplanin and any future products, the new legislation could adversely affect our anticipated revenues and results of operations, possibly materially.

Many health maintenance organizations and other third-party payers use formularies, or lists of drugs for which coverage is provided under a health care benefit plan, to control the costs of prescription drugs. Each payer that maintains a drug formulary makes its own determination as to whether a new drug will be added to the formulary and whether particular drugs in a therapeutic class will have preferred status over other drugs in the same class. This determination often involves an assessment of the clinical appropriateness of the drug and sometimes the cost of the drug in comparison to alternative products. We cannot assure you that FACTIVE tablets, Testim, 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.

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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 hospital, 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 exhibit, 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;

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; and

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

Over the two-year period ending March 31, 2005 the closing price of our common stock as reported on the Nasdaq National Market ranged from a high of $7.01 to a low of $1.45. The stock market has from time to time experienced extreme price and volume fluctuations that are unrelated to the operating performance of particular companies. In the past, companies that have experienced volatility have sometimes been the subject of securities class action litigation. If litigation were instituted on this basis, it could result in substantial costs and a diversion of management s attention and resources. These broad market fluctuations may adversely affect the price if 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.

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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, 2004. Our Annual Report on Form 10-K was filed with the Securities and Exchange Commission on March 16, 2005. There have been no material changes in the first three months of 2005 to such risks or our management of such risks.

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 first quarter of this fiscal year covered by this report, there have been no significant changes in internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II

Item 1. ***Legal Proceedings***

None

Item 2. ***Unregistered Sales of Equity Securities and Use of Proceeds***

None

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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***

Exhibit No.	Description
10.1	Amendment No. 4 to License and Option Agreement between Oscient Pharmaceuticals Corporation and LG Life Sciences, Ltd. dated March 31, 2005.*
10.2	Co-Promotion Agreement between Auxilium Pharmaceuticals, Inc. and Oscient Pharmaceuticals Corporation dated April 11, 2005.*
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, 2005

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OSCIENT PHARMACEUTICALS CORPORATION

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