OSCIENT PHARMACEUTICALS CORP
Form 10-Q
November 09, 2004
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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: September 25, 2004

¨ 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 ¨ No x

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

COMMON STOCK	**75,193,882 Shares**
$0.10 PAR VALUE	Outstanding November 5, 2004

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OSCIENT PHARMACEUTICALS CORPORATION AND SUBSIDIARIES

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PART 1 FINANCIAL INFORMATION

OSCIENT PHARMACEUTICALS CORPORATION AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS (UNAUDITED)

	December 31, 2003	September 25, 2004
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 20,969,292	$ 73,500,917
Marketable securities (held-to-maturity)	4,595,740	101,425,930
Marketable securities (available-for-sale)	3,100,000	
Restricted cash		5,034,169
Interest receivable	138,189	1,363,505
Accounts receivable	257,389	5,418,444
Inventory		5,661,911
Prepaid expenses and other current assets	120,852	2,934,424
Total Current Assets	29,181,462	195,339,300
Property and Equipment, at cost:		
Laboratory and scientific equipment	12,573,855	12,183,838
Leasehold improvements	7,516,159	7,605,649
Equipment and furniture	1,240,682	1,409,358
	21,330,696	21,198,845
Less Accumulated depreciation	18,009,495	18,361,475
	3,321,201	2,837,370
Restricted cash		14,160,722
Long-term marketable securities (held-to-maturity)		11,645,758
Note receivable from related party	6,238,219	
Other assets	1,775,433	5,674,919
Intangible assets		71,649,812
Goodwill		55,610,085
	$ 40,516,315	$ 356,917,966
LIABILITIES AND SHAREHOLDERS EQUITY		
Current Liabilities:		
Current maturities of long-term obligations	$ 1,166,667	$ 673,120
Accounts payable	1,523,633	6,059,882
Accrued expenses and other current liabilities	3,483,308	9,499,945
Accrued facilities impairment charge		2,384,012
Clinical trial expense accrual	3,652,604	4,280,327
Deferred revenue	458,333	2,075,693
Total Current Liabilities	10,284,545	24,972,979
Long-term Liabilities:		
Long-term obligations, net of current maturities	291,666	175,059,647

Accrued facilities impairment charge		12,913,396
Other long-term liabilities		889,923
Shareholders Equity:		
Common stock and additional paid-in capital	185,875,163	363,450,835
Accumulated deficit	(155,564,152)	(216,553,325)
Deferred compensation	(207,907)	(3,652,489)
Note receivable from officer	(163,000)	(163,000)
Total Shareholders Equity	29,940,104	143,082,021
	$ 40,516,315	$ 356,917,966

See Notes to Consolidated Financial Statements

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OSCIENT PHARMACEUTICALS CORPORATION AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

	Thirteen Week Period Ended		Thirty-Nine Week Period Ended	
	September 27, 2003	September 25, 2004	September 27, 2003	September 25, 2004
Revenues:				
Product sales	$	$ 1,380,648	$	$ 1,380,648
Biopharmaceutical	2,607,967	140,373	5,519,381	2,511,293
Genomics services and royalties	261,573	45,637	1,799,240	145,637
Total revenues	2,869,540	1,566,658	7,318,621	4,037,578
Costs and Expenses:				
Cost of product sales		1,194,843		1,194,843
Cost of services			1,902,561	
Research and development (1)	6,487,736	7,439,014	17,541,087	18,799,795
Selling, general and administrative (1)	1,458,391	14,237,326	5,124,867	27,128,327
Write-off of in-process technology at merger				11,704,396
Restructuring charge	742,166		4,732,914	98,649
Convertible debt retirement expense	12,500		5,540,333	
Stock based compensation	111,377	1,876,055	338,062	4,322,351
Total costs and expenses	8,812,170	24,747,238	35,179,824	63,248,361
Loss from operations	(5,942,630)	(23,180,580)	(27,861,203)	(59,210,783)
Other Income (Expense):				
Interest income	80,619	869,716	460,280	1,559,581
Interest expense	(23,653)	(2,019,278)	(995,977)	(3,560,163)
Gain (loss) on sale of fixed assets	73,636	86,629	(58,522)	222,192
Net other income (expense)	130,602	(1,062,933)	(594,219)	(1,778,390)
Net loss	$ (5,812,028)	$ (24,243,513)	$ (28,455,422)	$ (60,989,173)
Net Loss per Common Share:				
Basic and diluted	$ (0.22)	$ (0.32)	$ (1.16)	$ (0.89)
Weighted Average Common Shares Outstanding:				
Basic and diluted	25,956,357	74,661,879	24,581,226	68,626,874

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

Research and development	$	$ 1,263,877	$	$ 3,362,532
Selling, general and administrative	111,377	612,178	338,062	959,819
	$ 111,377	$ 1,876,055	$ 338,062	$ 4,322,351

See Notes to Consolidated Financial Statements.

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OSCIENT PHARMACEUTICALS CORPORATION AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

	Thirty-Nine Week Period Ended	
	September 27, 2003	**September 25, 2004**
Cash Flows from Operating Activities:		
Net loss	$ (28,455,422)	$ (60,989,173)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	2,109,412	3,988,233
Non-cash restructuring charge	3,700,075	
Non-cash convertible debt retirement expense	4,012,269	
Non-cash interest expense	1,225,454	770,631
Non-cash write-off of in process technology at merger		11,704,396
Loss (gain) on disposal of fixed assets	58,522	(213,142)
Amortization of deferred compensation	338,062	4,322,351
Changes in assets and liabilities		
Interest receivable	544,768	(1,225,316)
Accounts receivable	1,864,609	(4,186,696)
Prepaid expenses and other current assets	679,074	(3,048,607)
Accounts payable	(1,928,126)	3,706,693
Accrued expenses and other current liabilities	121,089	2,509,924
Clinical trial expense accrual	878,226	627,723
Deferred revenue	(713,797)	1,617,360
Accrued facilities impairment charge		(2,042,838)
Accrued other long-term liabilities		889,923
Net cash used in operating activities	(15,565,785)	(41,568,538)
Cash Flows from Investing Activities:		
Cash flow impact related to merger		(14,998,098)
Purchases of marketable securities	(5,281,108)	(141,362,948)
Proceeds from sale of marketable securities	30,674,413	35,987,000
Purchases of property and equipment	(106,445)	(686,573)
Proceeds from sale of property and equipment	470,269	682,747
Increase in restricted cash		(15,498,051)
Decrease (increase) in other assets	705,087	(4,223,584)
Net cash provided by (used in) investing activities	26,462,216	(140,099,507)
Cash Flows from Financing Activities:		
Gross proceeds from issuance of convertible notes		152,750,000
Proceeds from sale of common stock	500,000	80,864,186
Proceeds from exercise of stock options	360,643	1,291,861
Proceeds from issuance of stock under the employee stock purchase plan	453,499	302,964
Proceeds from exercise of warrants		194,880
Proceeds from a legal claim with an investor	584,711	
Payments made upon retirement of convertible notes payable	(10,000,000)	
Payments on long-term obligations	(2,753,731)	(1,204,221)
Net cash (used in) provided by financing activities	(10,854,878)	234,199,670

Net Increase in Cash and Cash Equivalents	41,553	52,531,625
Cash and Cash Equivalents, beginning of period	14,228,507	20,969,292
Cash and Cash Equivalents, end of period	$ 14,270,060	$ 73,500,917
Supplemental Disclosure of Cash Flow Information:		
Interest paid during period	$ 568,500	$ 41,435
Income tax paid during period	$ 24,999	$ 17,939
Supplemental Disclosure of Non-cash Investing and Financing Activities:		
Unrealized gain on marketable securities	$ 271,801	$
Issuance of warrant in connection with convertible notes payable	$ 149,781	$
Issuance of common stock related to interest payable under convertible notes	$ 581,096	$
Issuance of common stock upon conversion of convertible notes payable	$ 5,000,000	$
Deferred Compensation related to unvested stock options at merger	$	$ 7,701,247
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 AND SUBSIDIARIES

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, 2003 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 5, 2004.

(2) SUMMARY OF SIGNIFICANT BUSINESS AND ACCOUNTING POLICIES

Oscient Pharmaceuticals Corporation along with its subsidiaries (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. On April 13, 2004, the Company changed its name from Genome Therapeutics Corp. to Oscient Pharmaceuticals Corporation. 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 of mild-to-moderate severity and acute bacterial exacerbations of chronic bronchitis. On September 9, 2004, the Company announced the official launch of FACTIVE tablets to the medical community.

In addition, the Company is developing a novel antibiotic candidate, Ramoplanin, which is currently in clinical trials for the treatment of serious hospital-acquired infections. On August 10, 2004, the Company announced preliminary results of its Phase II trial of Ramoplanin for the treatment of Clostridium difficile-associated diarrhea (CDAD). Pending the outcome of a full analysis of the trial data with the FDA, including a Special Protocol Assessment, the Company plans to commence a Phase III trial for CDAD. In July 2004, the Company decided to close enrollment on its Phase III clinical trial of Ramoplanin for the prevention of bloodstream infections caused by vancomycin-resistant enterococci (VRE) prior to completion of the study. The Company intends to analyze the results of the VRE trial and make a determination at a later date as to any future course of action for this indication.

The Company s preclinical development programs include an oral peptide deformylase inhibitor series for the potential treatment of respiratory tract infections as well as development of a FACTIVE intravenous formulation. The Company also has six pharmaceutical alliances focused on the discovery and development of novel therapeutics for chronic human diseases and certain infectious diseases. These alliances were formed in previous years based on the Company s genomics expertise. It is no longer the Company s focus to pursue gene discovery or additional partnerships of this type.

The Company s strategic goal is to supplement its existing product and clinical candidates with additional therapeutic opportunities, either through in-licensing, co-promotion or through mergers with, and acquisitions of, appropriate companies.

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) Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Collaborative Securities Corp. (a Massachusetts Securities Corporation) and Genesoft. All intercompany accounts and transactions have been eliminated in consolidation.

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(b) Revenue Recognition

The Company s principal sources of revenue are sales of FACTIVE, which began shipping in the third quarter of 2004. Other sources of revenue include biopharmaceutical and royalties from the divested genomic services business. The Company expects its revenues derived from biopharmaceutical alliance and genomics services to continue to decrease and product revenues to increase based on the launch of the sale of FACTIVE tablets in September of 2004.

Biopharmaceutical Product Sales, net

The Company follows the provisions of Staff Accounting Bulletin No. 104, Revenue Recognition 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, the Company defers the recognition of revenue by recording deferred revenue until such time that risk of loss has passed.

Genomics-Based Research & Alliances and Genomics Services

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 exited these businesses and revenues will continue to decline from these sources.

Biopharmaceutical revenues have consisted of government research grants, and license fees, contract research and milestone payments from alliances with pharmaceutical companies. Genomics services revenues consist of government sequencing grants, fees and royalties received from custom gene sequencing and analysis services as well as subscription fees from the PathoGenome Database.

Revenues from contract research, government grants, and custom gene sequencing and analysis services are recognized over the respective contract periods as the services are performed, provided there is persuasive evidence of an arrangement, the fee is fixed or determinable and collection of the related receivable is reasonably assured. The percentage of services performed related to contract research, government grants and custom gene sequencing and analysis services is based on the ratio of the number of direct labor hours performed to date to total direct labor hours the Company is obligated to perform under the related contract, as determined on a full-time equivalent basis. Revenues from PathoGenome Database subscription fees are recognized ratably over the term of the subscription agreement. Revenues received for license fees are deferred and recognized ratably over the performance period. Milestone payments are recognized upon achievement of the milestone as long as the milestone is non-refundable, deemed to be substantive and the Company has no other performance obligations related to the milestone.

(c) Clinical Trial Expense Accrual

The Company s 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 the Company to estimate both the total cost and time period of the trials and the percent completed as of that accounting date. The Company also adjusts these estimates when final invoices are received. In July 2004, the Company decided to close enrollment on its Phase III clinical trial of Ramoplanin for the prevention of bloodstream infections caused by vancomycin-resistant enterococci (VRE) prior to completion of the study. The Company believes all actual and estimated costs to complete the Phase III trial are reflected in the accrual at September 25, 2004. However, readers should be cautioned that the possibility exists that the timing of the clinical trials might be longer or shorter and the cost could be more or less than we have estimated and that the associated financial adjustments would be reflected in future periods.

For the clinical development of Ramoplanin and FACTIVE, the Company recorded expenses of approximately $8,660,000, and $14,777,000 for the thirty-nine week periods ended September 27, 2003 and September 25, 2004, respectively.

(d) Property and Equipment

The Company records property, plant and equipment at cost. The Company depreciates its property over its estimated useful life using the straight-line method. 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
Laboratory Equipment	5 Years
Computer Equipment & Licenses	3 Years
Office Equipment	5 Years
Furniture & Fixtures	5 Years

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Depreciation expense was approximately $2,109,000 and $963,000 for the thirty-nine week periods ended September 27, 2003 and September 25, 2004, respectively.

(e) Inventory

Inventory is stated at the lower of cost or market with cost determined under the first-in/first-out (FIFO) method. As of September 25, 2004, inventory consists of FACTIVE raw material in powder form of approximately $1,958,000 and FACTIVE finished tablets of approximately $3,704,000 to be used for sample and commercial sale related to the product launch of FACTIVE in September 2004. 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 expected requirements to cost of product revenues. Expired inventory will be disposed of and the related costs will be written off. As of September 25, 2004, there has been no write-down of inventory.

(f) Net Loss Per Share

Basic and diluted net loss per share was determined by dividing net loss by the weighted average shares outstanding during the period. Diluted loss per share is the same as basic loss per share for all periods presented, as the effect of the potential common stock is 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 4,852,945 and 38,059,895 shares of the Company s common stock during thirty-nine week periods ended September 27, 2003 and September 25, 2004, respectively.

(g) Single Source Suppliers

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

(h) 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 Company maintains reserves for the potential write-off of accounts receivable. To date, the Company has not written off any significant accounts.

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	F	G	H
Thirteen-week period ended:									
September 27, 2003	3			10%	12%	62%			
September 25, 2004	3						25%	23%	12%
Thirty-nine week period ended:									
September 27, 2003	4	17%		11%	14%	47%			
September 25, 2004	3	34%				25%	10%		

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

	Number of Significant Customers	Percentage of Total Accounts Receivable by Customer							
		A	B	C	D	E	F	G	H
As of:									
December 31, 2003	2	21%	64%						
September 25, 2004	4	11%					35%	29%	14%

(i) 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.

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(j) Financial Instruments

The estimated fair value of the Company s financial instruments, which includes cash and cash equivalents, short-term and long-term marketable securities, accounts receivable, accounts payable and long-term debt, approximates the carrying values of these instruments.

(k) Reclassifications

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

(l) 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 the thirty-nine week period ended September 27, 2003, the Company recorded approximately $272,000 to comprehensive income related to the increase in fair market value of common shares. For the thirty-nine week period ended September 25, 2004, net loss equaled comprehensive loss.

(m) 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. To date, the Company has viewed its operations and manages its business as principally two operating segments: genomics services and biopharmaceutical. As a result, the financial information disclosed herein represents all of the material financial information related to the Company s two operating segments. All of the Company s revenues are generated in the United States and all assets are located in the United States (See Note 4).

	Biopharmaceutical Product Sales	Genomics Services	Genomics-Based Research & Alliances	Total
Thirty-nine week period ended September 27, 2003				
Revenues	$	$ 1,799,240	$ 5,519,381	$ 7,318,621
Gross profit (loss)		(103,321)	1,849,064	1,745,743

Company-funded research & development costs			13,870,770	13,870,770
Thirty-nine week period ended September 25, 2004				
Revenues	$ 1,380,648	$ 145,637	$ 2,511,293	$ 4,037,578
Gross profit	185,805	145,637	226,463	557,905
Company-funded research & development costs			16,514,965	16,514,965

Revenues from product sales are recorded net of applicable allowances for sales returns, rebates, discounts and chargebacks. Prior to the sale in 2003, the measure of gross profit for the Genomics Services segment is the total segment revenues less cost of services. After March 2003, the Company only receives royalties from such business. The measure of gross profit for the Biopharmaceutical segment is equal to total segment revenues less externally funded research and development costs related to the Company s alliance arrangements and government research grants. The Company does not allocate assets by operating segment.

(n) Long-Lived Assets

The Company follows the provisions of SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets (SFAS No. 144). SFAS No. 144 requires that long-lived assets be reviewed for impairment by comparing the future undiscounted cash flows from the assets with the carrying amount. Any write-downs are to be treated as permanent reductions in the carrying amount of the assets.

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The Company also follows the provisions of SFAS No. 142, Goodwill and Other Intangible Assets, (SFAS No. 142). Under SFAS 142, goodwill and purchased intangibles with indefinite lives acquired after June 30, 2001 are not amortized but are reviewed periodically for impairment. As of September 25, 2004, the Company does not believe that any of its long-lived assets, goodwill, and other intangible assets are impaired.

(o) Pro Forma Disclosure of Stock-based Compensation

The Company follows Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees (APB 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, Accounting for Stock-Based Compensation. Under APB 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) 96-18, the Company records compensation expense equal to the fair value of options granted to non-employees over the vesting period, which is generally the period of service.

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.

	Thirteen week Period Ended		Thirty-Nine week Period Ended	
	September 27, 2003	September 25, 2004	September 27, 2003	September 25, 2004
Net loss as reported	$ (5,812,028)	$ (24,243,513)	$ (28,455,422)	$ (60,989,173)
Add: Stock-based employee compensation cost, included in the determination of net loss as reported	111,377	1,876,055	338,062	4,322,351
Less: Total stock-based compensation expense determined under the fair value method for all employee awards	(550,234)	(5,581,741)	(1,850,283)	(8,045,707)
Pro forma net loss	$ (6,250,885)	$ (27,949,199)	$ (29,967,643)	$ (64,712,529)
Basis and diluted net loss per share				
As reported	$ (0.22)	$ (0.32)	$ (1.16)	$ (0.89)
Pro forma	$ (0.24)	$ (0.37)	$ (1.22)	$ (0.94)

The Company s stock option grants vest over several years and the Company intends to grant varying levels of stock options in the future periods. Therefore, the pro forma effects on 2003 and 2004 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 are not necessarily representative of the effects on reported results from operations for future years.

(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. The acquisition was accounted for as a purchase in accordance with SFAS No. 141, Accounting for Business Combinations and accordingly, allocated the purchase price of Genesoft upon the estimated fair value of net assets acquired and liabilities assumed. The purchase price of approximately $108 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.

The following is a summary of the Company s estimate of the fair values of the assets acquired and liabilities assumed at the date of acquisition. The Company engaged a third party to appraise the fair value of the acquired tangible and intangible assets, which has completed its report. The Company has completed its analysis of the fair values of the liabilities assumed in connection with the acquisition, including certain liabilities that qualify for recognition under Emerging Issues Task Force 95-3 Recognition of Liabilities in connection with a Purchase Business Combination . The Company has finalized the purchase price allocation by completing analysis of its assumed liabilities and other relevant information relating to the acquisition. The final purchase price allocation is presented below:

Assets:	
Current Assets	$ 6,683
Property & Equipment	263
Intangible Assets Subject to Amortization	74,675
Restricted Cash	3,697
In-Process Research & Development	11,704
Goodwill	55,610
Total Assets Acquired	$ 152,632
Liabilities:	
Current Liabilities	$ 5,199
Long Term Liabilities	22,310
Accrued Facility Costs	16,887
Total Liabilities Acquired	$ 44,396
Net Assets Acquired	$ 108,236

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The valuation of the purchased intangible assets of $74.7 million was based on the result of a valuation using the income approach and applying a risk adjusted discount rate between 15% and 22%. The valuation of purchased intangible assets includes Genesoft s lead product and developed technology, FACTIVE, valued at $69.5 million, an orally administered, broad-spectrum fluoroquinolone antibiotic which was approved by the FDA for the treatment of acute bacterial exacerbation of chronic bronchitis (ABECB) and community-acquired pneumonia (CAP) of mild to moderate severity. The valuation of purchased intangible assets also includes the value of a manufacturing and supply agreement for FACTIVE with a third party of $5.2 million. Both intangibles will be amortized over the life of the patent which is approximately 16 years, resulting in approximately $4.6 million of amortization expense on an annual basis. For the nine months ended September 25, 2004, the Company has recorded approximately $3.0 million in amortization expense.

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 $1,441,000 in severance-related costs and $16,887,000 in facility lease impairment costs. Through September 25, 2004, the Company paid $925,000 against the accrual for severance-related costs and $2,043,000 against the facility lease costs.

Additionally, the Company recorded approximately $7,701,000 of deferred compensation related to the intrinsic value of unvested options issued in exchange for options assumed in the merger. The Company recorded approximately $4,160,000 in amortization of deferred compensation through September 25, 2004 in connection with the merger.

Supplemental Pro Forma Information:

The unaudited pro forma combined condensed statements of operations for the thirty-nine week period ended September 25, 2004 and September 27, 2003 gives effect to the acquisition of Genesoft as if the acquisition of Genesoft had occurred on January 1, 2004 and 2003, respectively.

The unaudited pro forma combined condensed statements of operations are not necessarily indicative of the financial results that would have occurred if the Genesoft acquisition had been consummated on January 1, 2003 nor are they necessarily indicative of the financial results which may be attained in the future.

The pro forma statements of operations are based upon available information and upon certain assumptions that the Company s management believes are reasonable. The Genesoft acquisition is being accounted for using the purchase method of accounting.

	Thirty-Nine weeks Ended (In thousands, except per share data)			
	September 25, 2004 (Actual)	**September 25, 2004 (Pro forma)**	**September 27, 2003 (Actual)**	**September 27, 2003 (Pro forma)**
Revenue	$ 4,038	$ 4,471	$ 7,319	$ 13,297
Total costs and expenses	65,027	67,920	35,774	84,165

Net loss	$ (60,989)	$ (63,449)	$ (28,455)	$ (70,868)
Weighted average number of shares basic and diluted	68,627	68,627	24,581	36,284
Net loss per share	$ (0.89)	$ (0.92)	$ (1.16)	$ (1.95)

The pro-forma adjustments include additional amortization expense of $623,000 for the thirty-nine week period ended September 25, 2004 and $5,607,000 for the thirty-nine week period ended September 27, 2003 related to deferred compensation and intangible assets.

(4) RESTRUCTURING PLAN

As part of our effort to reduce costs and expenses, the Company adopted a plan in 2003 to substantially reduce its research effort in internally funded early-stage discovery programs under its Genomics-Based Research & Alliances operating segment. Under this plan, the

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Company eliminated 44 full-time positions and recorded a restructuring charge of approximately $5.3 million in 2003 and $99,000 for the thirty-nine week period ended September 25, 2004. The following table displays the restructuring activity and liability balance included in accrued expenses.

Year Ended December 31, 2003

	Balance at December 31, 2002	Charges	Cash Payments	Asset Impairment	Stock Option Compensation	Balance at December 31, 2003
Termination benefits	$	$ 1,507,521	$ (708,489)	$	$ (186,791)	$ 612,241
Asset impairment		3,749,741		(3,749,741)		
	$	$ 5,257,262	$ (708,489)	$ (3,749,741)	$ (186,791)	$ 612,241

Thirty-nine week Period Ended September 25, 2004

	Balance at December 31, 2003	Charges	Cash Payments	Asset Impairment	Stock Option Compensation	Balance at September 25, 2004
Termination benefits	$ 612,241	$ 98,649	$ (608,890)	$	$	$ 102,000

Costs of termination benefits relate to severance packages, outplacement services and a non-cash charge for the acceleration of vesting of previously granted stock options for employees affected by the initiative. The remaining termination benefits relate to accrued outplacement service expenses, which will be paid out during the next three months of 2004. The Company s decision to terminate certain research programs and to vacate laboratory space was deemed to be impairment indicators under SFAS No. 144, Accounting for Impairment of Disposal of Long-Lived Assets. As a result of performing the impairment evaluations, asset impairment charges were recorded during the second quarter of 2003 to adjust the carrying value of the related long-lived assets to their net realizable value. The Company sold a portion of these long-lived assets and recorded a gain of approximately $222,000 through September 25, 2004. At September 25, 2004, the net realized value of the remaining long-lived assets on hand was approximately $193,000. The Company plans to sell these assets over the next three months.

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

Thirty-nine week Period Ended September 25, 2004

	Balance at December 31, 2003	Liability recorded	Cash Payments	Amortization	Balance at September 25, 2004

Termination benefits	$	$ 1,440,685	$ (924,618)	$	$ 516,067
Lease liability		16,886,749	(2,042,838)	453,497	15,297,408
	$	$ 18,327,434	$ (2,967,456)	$ 453,497	$ 15,813,475

In addition, the Company recorded interest expense of approximately $453,000 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.

(5) CASH EQUIVALENTS AND INVESTMENTS

The Company applies the provisions of SFAS No. 115, Accounting for Certain Investments in Debt and Equity Securities. At December 31, 2003 and September 25, 2004, the Company s investments included short-term and long-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 September 25, 2004, the average maturity of the Company s investments was approximately 6.5 months. Also, at September 25, 2004, the Company had a net unrealized loss of approximately $108,000, which is the difference between the amortized cost and the fair value of the held-to-maturity investments.

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At September 25, 2004, the Company s short-term marketable securities (held-to-maturity) are carried at amortized cost which approximates estimated market value.

At December 31, 2003 and September 25, 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
December 31, 2003				
Cash and Cash Equivalents:				
Cash	$ 17,208,907	$	$	$ 17,208,907
Debt securities	3,760,385	325	(1,335)	3,759,375
Total cash and cash equivalents	$ 20,969,292	$ 325	$ (1,335)	$ 20,968,282
Investments (held-to-maturity):				
Short-term marketable securities	$ 4,595,740	$ 692	$ (2,985)	$ 4,593,447
Investments (available-for-sale):				
Short-term marketable securities	$ 3,100,000	$	$	$ 3,100,000
September 25, 2004				
Cash and Cash Equivalents:				
Cash	$ 53,791,514	$	$	$ 53,791,514
Debt securities	19,709,403	1,382		19,710,785
Total cash and cash equivalents	$ 73,500,917	$ 1,382	$	$ 73,502,299
Investments (held-to-maturity):				
Short-term marketable securities	$ 101,425,930	$ 33,968	$ (147,587)	$ 101,312,311
Long-term marketable securities	11,645,758	6,514	(2,444)	11,649,828
Total investments (held-to-maturity)	$ 113,071,688	$ 40,482	$ (150,031)	$ 112,962,139

(6) NOTE RECEIVABLE

At the time of the signing of the merger agreement with Genesoft on November 17, 2003, the Company made a bridge loan of $6.2 million with an interest rate of 5% per annum to Genesoft pursuant to a promissory note. This note receivable and related interest owed was assumed in the merger and, accordingly, was included in the purchase price of this merger transaction.

(7) LONG-TERM OBLIGATIONS

The Company has a loan agreement for $3,500,000 which is payable in twelve consecutive quarterly payments at the prevailing LIBOR rate (1.97% at September 25, 2004) plus 1.50%. The Company is required to maintain certain financial covenants pertaining to minimum cash balances. As of September 25, 2004, $583,333 was outstanding under the loan agreement and the Company was in compliance with all of the covenants.

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, following the one year anniversary of the closing of the merger, 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.

In the thirty-nine week period ended September 25, 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 change of control or a termination of trading of the Company s common stock (each as defined in the indenture for the notes), 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 cash purchase of the Company s common stock, 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 $5,708,420 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 September 25, 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.

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(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 quinolone antibiotic, in North America, France, Germany, the United Kingdom, Luxembourg, Ireland, Italy, Spain, Portugal, Belgium, the Netherlands, Austria, Greece, Sweden, Denmark, Finland, Norway, Iceland, Switzerland, Andorra, Monaco, San Marino and Vatican City. The term of the agreement with respect to each country extends at least through the life of the patents covering gemifloxacin in such country. In the United States, the last of the currently issued patents 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 the Company is 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. LG Life Sciences has an agreement with SB Pharmco pursuant to which SB Pharmco will supply finished FACTIVE product to LG Life Sciences. The term of this agreement was to expire on June 30, 2004, but was extended by LG Life Sciences to complete existing orders and product commitments already in the supply chain pipeline. The Company has initiated the technology transfer process with a new provider of finished products, who will assume these responsibilities for subsequent periods. We estimate that a new provider of finished FACTIVE product will obtain the necessary FDA qualifications by the second half of 2005. The Company expects to obtain quantities of FACTIVE tablets from SB Pharmco that will provide us with sufficient inventory until the new provider can be qualified.

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.

Under this license agreement, we were required to pay LG Life Sciences $8 million upon the completion of the merger with Genesoft. The arrangement also provides for potential additional milestone payments to LG Life Sciences of up to $22 million upon obtainment of additional regulatory approvals and sales targets. 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.

(9) MAJOR RESEARCH AND DEVELOPMENT PROJECTS

In October 2001, the Company acquired an exclusive license in the United States and Canada for a novel antibiotic, Ramoplanin, from Biosearch Italia S.p.A (which merged with Versicor in March 2003 and subsequently changed its name to Vicuron). The Company has assumed responsibility for the product development in the United States of Ramoplanin. During the third quarter, the Company closed enrollment for the Phase III clinical trial for the prevention of bloodstream infections caused by vancomycin-resistant enterococci (VRE) prior to completion of the study and will make a determination at a later date as to any future course of action for this indication. On August 10, 2004, the Company announced preliminary results of its Phase II clinical trial to assess the safety and efficacy of Ramoplanin to treat Clostridium difficile-associated diarrhea (CDAD). Initiation of a Phase III study is subject to a full analysis of the data from the Phase II trial and successful planning discussions with the FDA, including a Special Protocol Assessment. The agreement provides the Company with exclusive rights to develop and

market oral Ramoplanin in the U.S. and Canada. Vicuron will provide the bulk material for manufacture of the product and will retain all other rights to market and sell Ramoplanin.

Under the terms of this agreement, the Company paid Vicuron an initial license fee of $2 million and is obligated to make payments of up to $8 million in a combination of cash and notes convertible into Company stock upon the achievement of specified milestones. In addition, the Company is obligated to purchase bulk material from Vicuron, fund the completion of clinical trials and pay a royalty on product sales.

(10) 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 exited these businesses and no longer conducts research in these areas.

Research and development expenses primarily consist of salaries and related expenses for personnel and the cost of materials and supplies used in research and development. Other research and development expenses include fees paid to consultants and outside service providers, information technology and facilities costs. The Company charges all research and development expenses to operations as incurred. The research and development expenses related to biopharmaceuticals revenues generally consist 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(b).

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The Company tracks actual costs related to each of its government grants, but it does not track 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 does, however, track total costs in the aggregate for its alliance and government grant arrangements separately from its internal research and development programs. During the thirty-nine week periods ended September 27, 2003 and September 25, 2004, the Company incurred expenditures of approximately $3,670,000 and $2,285,000, respectively, related to its alliances and government grants.

The Company has completed its obligations under its alliances with AstraZeneca, 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 we 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 will retain certain intellectual property and licensing rights related to its gene discovery. Under this alliance, the Company received approximately $5.8 million through September 25, 2004, 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 approximately $3,415,000 and $1,013,000, in revenue during the thirty-nine week periods ended September 27, 2003 and September 25, 2004, respectively, which consisted of alliance research revenue and amortization of the up-front license fee.

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

Certain information contained in this report should be considered 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, and (iv) inability to obtain adequate distribution in wholesalers and pharmacies;

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, 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 ability 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.

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We have included more detailed descriptions of these and other risks and uncertainties under the heading Factors Affecting Future Operating Results 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 with Genesoft 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 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 product portfolio is led by the FDA-approved 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 was launched in September 2004. For the near term, we intend to focus our efforts on the launch of commercial sales of FACTIVE tablets for these indications as well as clinical trials for other indications of FACTIVE.

The Company completed its initial recruitment of over one-hundred sales and marketing professionals in September 2004 to launch the sale of FACTIVE tablets and has begun to recruit and hire an additional one-hundred fifty sales and marketing professionals to support a nationwide sales force for FACTIVE. With the launch of FACTIVE tablets in September of 2004, the Company does not expect sales of FACTIVE tablets to have a significant impact on the Company s operating results in 2004, with the majority of revenue representing wholesale and pharmacy stocking.

In addition, we are developing a novel investigational antibiotic candidate, Ramoplanin, which is currently in clinical trials for the treatment of serious hospital-acquired infections. 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 the outcome of a full analysis of the trial data and discussions with the FDA, including a Special Protocol Assessment, we plan to commence a Phase III trial for CDAD in 2005. In July 2004, we decided to close enrollment on the Phase III clinical trial of Ramoplanin for the prevention of bloodstream infections caused by vancomycin-resistant enterococci (VRE) prior to completion of the study. We intend to analyze the results of the VRE trial and make a determination at a later date as to any future course of action for this indication.

In the first quarter of 2003 and 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. We have received a total of $730,000 from Agencourt since March 14, 2003.

Previously, we received payments from our product discovery alliances based on license fees, contract research and milestone payments during the term of our alliances. We anticipate that our alliances will 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, which was launched in September of 2004.

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We have incurred significant operating losses since our inception. As of September 25, 2004, we had an accumulated deficit of approximately $216.6 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 and third quarters of 2004, we built a sales and marketing force in order to permit the launch of FACTIVE tablets in September of 2004. We began the launch of FACTIVE tablets on September 9. However, we do not expect sales of FACTIVE tablets to have a significant impact on our operating results in 2004.

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.

Major Research and Development Projects

FACTIVE (gemifloxacin mesylate) Tablets

Our ongoing clinical trials and other development activities for the FACTIVE product for the thirty-nine week period ended September 25, 2004 totaled approximately $8,090,000. 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 quinolone antibiotic, in North America, France, Germany, the United Kingdom, Luxembourg, Ireland, Italy, Spain, Portugal, Belgium, the Netherlands, Austria, Greece, Sweden, Denmark, Finland, Norway, Iceland, Switzerland, Andorra, Monaco, San Marino and Vatican City. The term of the agreement with respect to each country extends at least through the life of the patents covering gemifloxicin 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 our agreement, LG Life Sciences has agreed to supply and we are obligated to purchase from LG Life Sciences all of our anticipated commercial requirements for FACTIVE bulk drug. LG Life Sciences is expected to supply the FACTIVE bulk drug substance from its manufacturing facility in South Korea. LG Life Sciences has an agreement with SB Pharmco pursuant to which SB Pharmco will supply finished FACTIVE product to LG Life Sciences. The original term of this agreement ended on June 30, 2004, but was extended by LG Life Sciences to complete existing orders and product commitments already in the supply chain pipeline. We have initiated the technology transfer process with a new provider of finished products, which will assume these responsibilities for subsequent periods. We estimate that a new provider of finished FACTIVE product will obtain the necessary FDA qualifications by the second half of 2005. We expect to obtain quantities of FACTIVE tablets from SB Pharmco that will provide us with sufficient inventory until the new provider can be qualified.

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.

Under this license agreement, we were required to pay LG Life Sciences $8 million upon the completion of the merger with Genesoft. The arrangement also provides for potential additional milestone payments to LG Life Sciences of up to $22 million upon obtainment of additional regulatory approvals and sales targets. 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.

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 ABECB. 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 during the next 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 fails 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 also initiated a study 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 are developing an intravenous formulation of gemifloxacin. We expect that this intravenous formulation will undergo a Phase I bioequivalence study in the coming months. Pending a successful outcome of the first study, we plan to conduct a single Phase III trial of the intravenous formulation before pursuing market approval from the FDA. Due to the risk 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.

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Ramoplanin

Our ongoing clinical trials and other development activities for Ramoplanin have constituted our most significant research and development projects comprising 49% and 35% of total research and development expenditures for thirty-nine week periods ended September 27, 2003 and September 25, 2004, respectively. Expenses for Ramoplanin have comprised 44% 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 Biosearch Italia S.p.A, which merged with Versicor Inc. (Versicor) in March 2003. Subsequently, Versicor changed its name to 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. Pending the outcome of a full analysis of the trial data and discussions with the FDA, including a Special Protocol Assessment, the Company plans to commence a Phase III trial. In July 2004, the Company decided to close enrollment on its Phase III clinical trial of Ramoplanin for the prevention of bloodstream infections caused by VRE prior to completion of the study. The Company intends to analyze the results of the VRE trial and make a determination at a later date as to any future course of action for this indication.

In addition, as of September 25, 2004, the Ramoplanin clinical program activities also included:

A pilot study to examine Ramoplanin s potential role in controlling the spread of nosocomial bacteria.

Other supportive clinical trials, Chemistry Manufacturing Controls (CMC), and development activity, such as formulation, scale-up and validation, required for registration are ongoing or being planned.

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 Pharmaceuticals Inc. indicating that they intend to seek to terminate the License and Supply Agreement between Vicuron and Oscient and reacquire rights to Ramoplanin. In their 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 their 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 will address this issue 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.

Genomics-Based Research & Alliances

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 exited these businesses and no longer conducts research in these areas.

Prior to April 7, 2004, one of the major research and development focus of ours was the support we provided to fulfill our research obligations with our pharmaceutical company partners under our strategic alliances.

The research and development expense to support these alliances was 21% and 12% of total research and development expenses for the thirty-nine week periods ended September 27, 2003 and September 25, 2004, respectively. Research and development expense to support our alliances was 34% of the total research and development expense from January 1, 1995 through September 25, 2004. The research phase of our alliances has ended as of April 7, 2004.

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A summary of the specific biopharmaceutical alliances that have composed our research and development program, including date initiated, alliance goal and status of each alliance, follows:

Biopharmaceutical Alliances	Goal	Status
AstraZeneca, August 1995	Develop pharmaceutical, vaccine and diagnostic products effective against gastrointestinal infections or any other disease caused by *Helicobacter pylori (H. pylori).*	The contract research phase of the alliance concluded in August 1999 and the program transitioned into AstraZeneca s pipeline. The program is currently in the lead optimization phase.
Schering-Plough, December 1995	Identify new gene targets for the development of novel antibiotics utilizing our *Staphylococcus aureus (S. aureus)* genomic database.	We completed our research obligations in March 2002 and validated drug targets and assays were turned over to Schering-Plough. Schering-Plough has advanced the program into high-throughput screening for drug candidates.
Schering-Plough, December 1996	Develop new pharmaceuticals for the treatment of asthma through the identification of genes and associated proteins.	In December 2002, we completed our research obligations and Schering-Plough has advanced the program into high-throughput screening for drug candidates.
Schering-Plough, September 1997	Development of new pharmaceutical products to treat fungal infections.	We completed our research obligations in March 2002 and validated drug targets and assays were turned over to Schering-Plough. Schering-Plough has advanced the program into high-throughput screening for drug candidates.
bioMerieux, September 1999	Develop, manufacture and sell *in vitro* pathogen diagnostics products for human clinical and industrial applications.	In November 2003, we completed our contract research obligations under the terms of this agreement.
Wyeth, December 1999	Develop drugs based on our genetic research to treat osteoporosis.	In December 2003, we completed our research obligations and Wyeth has advanced the program into high-throughput screening for drug candidates.
Amgen, December 2002	Identify and develop novel therapeutic agents for bone diseases, including osteoporosis based on our genetic research.	Both companies agreed to conclude the research collaboration effective April 7, 2004. With the conclusion of this research program, we will retain certain intellectual property and licensing rights related to its gene discovery under this alliance.

Our ability to obtain the goal for each of these alliances is subject to numerous risks. We are heavily dependent upon our alliance partners to carry out product discovery, clinical development and commercialization activities. Our success in achieving our goals and obtaining further milestone payments depends, for example, 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. Due to these uncertainties, we can not be certain if we will obtain additional milestone payments under our alliances or predict when material cash inflows from products generated by these alliances will commence, if ever.

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.

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As a combined category, these research efforts represented 30% and 10% of total research and development expenses for the thirty-nine week periods ended September 27, 2003 and September 25, 2004, respectively. These efforts comprised 46% of the total research and development expense from January 1, 1995 through September 25, 2004.

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

Principal sources of revenue are sales of FACTIVE, which began shipping in the third quarter of 2004. Other sources of revenue include biopharmaceutical and genomic services. We expect our revenues derived from both our biopharmaceutical alliance and genomics services to continue to decrease in comparison to prior years and an increase in product revenues based on the launch of the sale of our FACTIVE tablets in September of 2004.

- Product Sales, net

We follow the provisions of Staff Accounting Bulletin No. 104 Revenue Recognition and we recognize revenue from product sales upon delivery of product to wholesalers, when persuasive evidence of an arrangement exists, the fee is fixed or determinable, title to product and associated risk of loss has passed to the wholesaler and collection of the related receivable is reasonably assured. For arrangements where risk of loss has not passed to the wholesalers or pharmacies, we defer the recognition of revenue by recording deferred revenue until such time that risk of loss has passed.

As is common in the pharmaceutical industry, 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, administrative fees, and other rebates. 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. Since FACTIVE is a new product, 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.

- Genomics-Based Research & Alliances and Genomics Services

Genomics-Based Research and Alliances revenues have consisted of government grants, license fees and contract research and milestone payments from alliances with pharmaceutical companies. Genomics services revenues have consisted of government grants, fees and royalties received from custom gene sequencing and analysis services and subscription fees from the PathoGenome Database.

Revenues from contract research, government grants, and custom gene sequencing and analysis services are recognized over the respective contract periods as the services are performed, provided there is persuasive evidence of an arrangement, the fee is fixed or determinable and collection of the related receivable is reasonably assured. The percentage of services performed related to contract research, government grants and custom gene sequencing and analysis services is based on the ratio of the number of direct labor hours performed to date to total direct labor hours we are obligated to perform under the related contract, as determined on a full-time equivalent basis. Revenues from PathoGenome Database subscription fees are recognized ratably over the term of the subscription agreement.

Amounts received for license fees are deferred and recognized ratably over the performance period. Milestone payments are recognized upon achievement of the milestone as long as the milestone is non-refundable, is deemed to be substantive and we have no other performance obligations related to the milestone. Unbilled costs and fees represent revenue recognized prior to billing. Deferred revenue represents amounts received prior to revenue recognition.

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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 September 25, 2004, 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. In July 2004, the Company decided to close enrollment on it Phase III clinical trial of Ramoplanin for the prevention of bloodstream infections caused by vancomycin-resistant enterococci (VRE) prior to completion of the study. All actual and estimated costs to complete the Phase III trial are reflected in the accrual at September 25, 2004. 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

Thirteen-Week Periods Ended September 27, 2003 and September 25, 2004

Revenues

Total revenues decreased 45% from $2,870,000 for the thirteen-week period ended September 27, 2003 to $1,567,000 for the thirteen-week period ended September 25, 2004.

Product sales increased from $0 for the thirteen-week period ended September 27, 2003 to $1,381,000 for the thirteen-week period ended September 25, 2004 due to the launch of commercial sale of FACTIVE tablets in September 2004.

Biopharmaceutical revenues decreased 95% from $2,608,000 for the thirteen-week period ended September 27, 2003 to $140,000 for the thirteen-week period ended September 25, 2004, primarily due to the reduction of revenues from alliances as a result of the conclusion of research agreements.

Revenues from Genomics Services decreased 83% from $262,000 for the thirteen-week period ended September 27, 2003 to $46,000 for the thirteen-week period ended September 25, 2004. These revenues from both periods were comprised of royalty payment as a result of the sale of our Genomics Services business to Agencourt. Revenues from the genomics services business will terminate in 2005 upon the expiration of our agreement with Agencourt.

There will be a shift in the revenue mix in 2004. We expect our revenues derived from both our biopharmaceutical alliance and genomics services to continue to decrease in comparison to prior years and an increase in product revenues based on the launch of the sale of FACTIVE tablets in September of 2004.

Costs and Expenses

Total costs and expenses increased 181% from $8,812,000 for the thirteen-week period ended September 27, 2003 to $24,747,000 for the thirteen-week period ended September 25, 2004.

Cost of product sales increased from $0 for the thirteen-week period ended September 27, 2003 to $1,195,000 for the thirteen-week period ended September 25, 2004 due to the launch of FACTIVE tablets in September 2004. Included in the cost of product sales is $770,000 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, amortization of intangible assets, and the cost of materials used in sequencing activities and research and development. Other research and development expenses include fees paid to consultants and outside service providers, information technology and facilities costs. Research and development expenses increased 15% from $6,488,000 for the thirteen-week period ended September 27, 2003 to $7,439,000 for the thirteen-week period ended September 25, 2004. This increase is primarily due to an increase of $4,700,000 in connection with the start of clinical trials for FACTIVE related to the 5 day CAP study and the FACTIVE intravenous formulation study as well as an increase of $2,300,000 in connection with feasibility testing of FACTIVE manufacturing in a new contracted manufacturing site. Offsetting this increase are a decrease of $4,600,000 in connection with the termination of the Ramoplanin VRE trial in July 2004, as well as decreases of $1,000,000 and $456,000 in cost of biopharmaceuticals revenues and internal research effort respectively.

As part of our continued effort to restructure our internally funded research programs associated with early-stage drug development, we recorded a restructuring charge of approximately $742,000 for the thirteen-week period ended September 27, 2003 related to severance costs and outplacement.

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Selling, general and administrative expenses increased 876% from $1,458,000 for the thirteen-week period ended September 27, 2003 to $14,237,000 for the thirteen-week period ended September 25, 2004. The increases in selling, general and administrative expenses is due to increased sales and marketing personnel and related costs of $6,142,000, increased other selling and marketing costs of approximately $1,741,000 to support the launch of FACTIVE, increased advertising and promotional costs of $3,931,000, increased general and administrative personnel, hiring and consulting costs of approximately $690,000 and increased legal and patent costs of approximately $275,000. Selling, general and administrative expenses are expected to increase in the foreseeable future as we continue to expand our commercialization efforts related to FACTIVE by adding an additional 150 sales representatives to support a national sales campaign.

Stock-based compensation increased from $111,000 for the thirteen-week period ended September 27, 2003 to $1,876,000 for the thirteen-week period ended September 25, 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 from $81,000 for the thirteen-week period ended September 27, 2003 to $870,000 for the thirteen-week period ended September 25, 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 from $24,000 for the thirteen-week period ended September 27, 2003 to $2,019,000 for the thirteen-week period ended September 25, 2004, primarily due to interest expense of approximately $1,351,000 related to the issuance of $153 million of senior convertible notes in the second quarter of 2004, $287,000 related to the issuance of $22 million of convertible notes in connection with the Genesoft merger, $200,000 related to amortization of deferred financing costs along with $170,000 related to non-cash interest expense related to the facility lease liability which was recorded during the quarter ended March 27, 2004.

For the thirteen week period ended September 27, 2003, we recorded a gain on the sale of fixed assets of $74,000. For the thirteen week period ended September 25, 2004, we recorded a gain on the sale of fixed assets of $87,000 primarily due to the sale of laboratory and computer equipment, which were no longer used in operations.

Thirty-nine week Periods Ended September 27, 2003 and September 25, 2004

The results of operations for the thirty-nine week period ended September 25, 2004 include the operations of Genesoft from February 6, 2004 to September 25, 2004.

Revenues

Total revenues decreased 45% from $7,319,000 for the thirty-nine week period ended September 27, 2003 to $4,038,000 for the thirty-nine week period ended September 25, 2004.

Product sales increased from $0 for the thirty-nine week period ended September 27, 2003 to $1,381,000 for the thirty-nine week period ended September 25, 2004 due to the launch of commercial sale of FACTIVE tablets in September 2004.

Biopharmaceutical revenues decreased 55% from $5,519,000 for the thirty-nine week period ended September 27, 2003 to $2,511,000 for the thirty-nine week period ended September 25, 2004 primarily due to the reduction of revenues from alliances as a result of the conclusion of research agreements.

Revenues from Genomics Services decreased 92% from $1,799,000 for the thirty-nine week period ended September 27, 2003 to $146,000 for the thirty-nine week period ended September 25, 2004 primarily due to the expiration of our government grants with the National Human Genome Research Institute to participate in the Human Genome and Mouse (Rat) Genome sequencing projects, as well as the sale of our Genomics Services business to Agencourt.

There will be a shift in the revenue mix in 2004. We expect our revenues derived from both our biopharmaceutical alliance and genomics services to continue to decrease in comparison to prior years and an increase in product revenues based on the launch of FACTIVE tablets in September 2004.

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Costs and Expenses

Total costs and expenses increased 80% from $35,180,000 for the thirty-nine week period ended September 27, 2003 to $63,248,000 for the thirty-nine week period ended September 25, 2004. Cost of services decreased 100% from $1,903,000 for the thirty-nine week period ended September 27, 2003 to $0 for the thirty-nine week period ended September 25, 2004 due to the sale of the Genomics Services business to Agencourt in March 2003.

Cost of product sales increased from $0 for the thirty-nine week period ended September 27, 2003 to $1,195,000 for the thirty-nine week period ended September 25, 2004 due to the launch of FACTIVE tablets in September 2004. Included in the cost of product sales is $770,000 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, amortization of intangible assets, and the cost of materials used in sequencing activities and research and development. Other research and development expenses include fees paid to consultants and outside service providers, information technology and facilities costs. Research and development expenses increased 7% from $17,541,000 for the thirty-nine week period ended September 27, 2003 to $18,800,000 for the thirty-nine week period ended September 25, 2004. This increase was primarily due to the increase in our effort in clinical development research programs totaling $6,117,000, offset by the decrease in our effort in early stage product discovery and development research programs totaling $3,473,000.

As part of our merger with Genesoft, we recorded a one-time charge of $11,704,000 related to in-process research and development expenses associated with internally funded early-stage target discovery programs. The valuation of the in-process research and development of $11,704,000 represents a peptide deformylase inhibitor research program (PDF) for the development of GSQ-83698 and oral PDF inhibitors, licensed from British Biotech (now Vernalis) for the treatment of community-acquired infections. In-process research and development also includes three novel metalloenzyme bacterial targets from Vernalis from which the combined company may elect to initiate a drug discovery program to develop therapeutics directed against these targets. This amount was determined in the allocation of the purchase price of Genesoft

As part of our effort to restructure our internally funded research programs, we discontinued our research effort in early-stage target discovery and development programs in the area of bacterial and fungal infections. As a result, we eliminated 23 full-time positions and recorded a restructuring charge of approximately $4,733,000 in the second and third quarters of 2003, of which approximately $1,033,000 was related to a reduction in work force, such as severance costs and outplacement services, and of which approximately $3,700,000 consists of impairment charges related to the value of laboratory and computer equipment no longer used in operations.

During the second and third quarters of 2003, we also recorded a one-time charge to convertible debt retirement expense of $5,540,000 for the early conversion of convertible notes payable issued to two institutional investors in March 2002, which consisted of $3,862,000 for the fair value of the incremental shares issued under the Amendment, Redemption and Exchange Agreement dated June 4, 2003 with the investors, $150,000 for the incremental fair value of the exchange warrants using the Black-Scholes option pricing model, as well as $574,000 of unamortized closing costs related to the original agreement with the investors and $954,000 of unamortized cost related to the value of the original warrants issued to the investors.

Selling, general and administrative expenses increased 429% from $5,125,000 for the thirty-nine week period ended September 27, 2003 to $27,128,000 for the thirty-nine week period ended September 25, 2004. The increase in selling, general and administrative expenses is due to

increased sales and marketing personnel and related costs of approximately $8,387,000, increased other sales and marketing costs of $4,309,000 to support the launch of FACTIVE, increased advertising and promotional costs of $5,897,000, increased general and administrative personnel, hiring and consulting costs of approximately $2,369,000 and increased legal and patent costs of approximately $1,041,000. Selling, general and administrative expenses are expected to increase in the foreseeable future as we continue to expand our commercialization efforts related to FACTIVE by adding an additional 150 sales representatives to support a national sales campaign.

Stock-based compensation increased from $338,000 for the thirty-nine week period ended September 27, 2003 to $4,322,000 for the thirty-nine week period ended September 25, 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.

Other Income and Expense

Interest income increased 239% from $460,000 for the thirty-nine week period ended September 27, 2003 to $1,560,000 for the thirty-nine week period ended September 25, 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.

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Interest expense increased 257% from $996,000 for the thirty-nine week period ended September 27, 2003 to $3,560,000 for the thirty-nine week period ended September 25, 2004, primarily due to interest expense of approximately $2,017,000 related to the issuance of $153 million of senior convertible notes in the second quarter of 2004, $732,000 related to the issuance of $22 million convertible notes in connection with the merger, along with approximately $453,000 related to non-cash interest expense related to the facility lease liability which was recorded during the quarter ended March 27, 2004.

For the thirty-nine week period ended September 27, 2003, we recorded a loss on the sale of fixed assets of $59,000, primarily reflecting the transfer of fixed assets associated with the Genomics Services business to Agencourt. For the thirty-nine week period ended September 25, 2004, we recorded a gain on the sale of fixed assets of $222,000, primarily due to the sale of laboratory and computer equipment, which were no longer used in operations.

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 September 25, 2004, we had cash, cash equivalents and short-term and long-term marketable securities of approximately $205,767,000, which includes $19,195,000 of restricted cash.

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 change of control or a termination of trading of our common stock (each as defined in the indenture for the notes), holders of our notes have the right to require us to repurchase all or any portion of their notes at a price equal to 100% of the principal amount plus accrued and unpaid interest. In addition, in the case of a cash purchase of our common stock, we may have an obligation to pay an additional make-whole premium to our 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.

We have a loan agreement under which we have financed certain office and laboratory equipment and leasehold improvements. We had approximately $583,000 outstanding under this borrowing arrangement at September 25, 2004. Under this arrangement, we are required to maintain minimum levels of unrestricted cash. We had no additional borrowing capacity under this financing agreement at September 25, 2004.

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. 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, following the one year anniversary of the closing of the merger, 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 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 $15,566,000 and $41,569,000 for the thirty-nine week periods ended September 27, 2003 and September 25, 2004, respectively. Cash used in our operating activities for the thirty-nine week period ended

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September 25, 2004 was due primarily to our net loss and increases in interest receivable, accounts receivable, prepaid expenses and other current assets as well as decrease in accrued facility impairment charge. These uses of cash were partially offset by increases in accounts payable, accrued expenses, clinical trial expense accrual, deferred revenues, accrued other long-term liabilities, and non-cash expenses, such as depreciation and amortization expense, interest expense, and write-off of in-process technology. Cash used in operating activities for the thirty-nine week period ended September 27, 2003 was due primarily to our net loss and decreases in accounts payable and deferred revenue. These uses of cash were partially offset by decreases in interest receivable, accounts receivable, and prepaid expenses as well as increases in clinical trial expense accrual, accrued expenses and non-cash expenses, such as depreciation and amortization and interest expense.

Our investing activities used cash of approximately $140,100,000 for the thirty-nine week period ended and September 25, 2004 and provided cash of approximately $26,500,000 for the thirty-nine week period ended September 27, 2003. Cash used by our investing activities for the thirty-nine week period ended September 25, 2004 was primarily related to $14,998,000 of merger costs, net purchases of marketable securities of $105,375,000, increases in restricted cash of $15,498,000 and other assets of $4,224,000 as well as purchases of property and equipment of $687,000. These uses of cash were partially offset by proceeds from sale of property and equipment of $683,000. Cash provided by our investing activities for the thirty-nine week period ended September 27, 2003 was primarily due to net proceeds of marketable securities of $25,400,000, proceeds from sale of property and equipment of $470,000 and decrease in other assets of $705,000.

Capital expenditures totaled $687,000 for the thirty-nine week periods ended September 25, 2004 primarily consisting of purchases of computer and related equipment as well as office furniture and leasehold improvements for the new office facilities and $106,000 for the thirty-nine week periods ended September 27, 2003 primarily consisting of purchases of computer and related equipment.

Our financing activities provided cash of approximately $234,200,000 for the thirty-nine week period ended September 25, 2004, primarily due to net proceeds from the issuance of convertible notes of $152,750,000, net proceeds from issuance of stock through private placement of $80,864,000, proceeds from exercise of 767,921 stock options and warrants of $1,487,000 and proceeds from the issuance of 125,542 shares of stock under the employee stock purchase plan of $303,000. These proceeds were partially offset by payments of long-term obligations of $1,204,000. Our financing activities used cash of approximately $10,855,000 for the thirty-nine week period ended September 27, 2003 primarily due to payments on retirement of convertible notes payable of $10,000,000 and payments of long-term obligations of $2,800,000, partially offset by proceeds received from settlement of a legal claim of $585,000 and the proceeds from the sale of common stock, exercise of stock options and issuance of stock under the employee stock purchase plan of $500,000, $361,000 and $453,000, respectively.

At December 31, 2003, we had net operating loss carryforwards of approximately $144,170,000 and $120,939,000, available to reduce federal and state taxable income respectively, if any. In addition, we also had tax credit carryforwards of approximately $12,240,000 to reduce federal and state income tax, if any. Net operating loss carryforwards are subject to review and possible adjustment by the Internal Revenue Service and may be limited in the event of certain cumulative changes in ownership interests of significant shareholders over a three-year period in excess of 50%. Additionally, certain of our losses have begun to expire due to time, not limitations.

We believe that, under our current rate of investment in development programs, as well as our effort to launch FACTIVE, that our existing capital resources, including the $81 million received from the sale of our common stock in connection with our offering related to the merger with Genesoft and proceeds from our $153 million senior convertible notes offering are adequate for at least thirty months of operations. 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 and expect to continue to experience a significant increase in hiring as we build a sales and marketing organization in order to launch 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 during 2004 and 2005 and we are in the process of hiring an

additional 150 sales and marketing professionals to support a nationwide sales force for FACTIVE.

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Contractual Obligations

Our major outstanding contractual obligations relate to our convertible promissory note and our facility leases. 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):

	2004	2005	2006	2007	2008	2009 & Thereafter
Operating Leases	$ 1,415	$ 5,817	$ 5,990	$ 5,098	$ 5,424	$ 12,002
Sublease Income	(746)	(3,008)	(2,939)	(1,966)	(2,035)	(3,372)
	$ 669	$ 2,809	$ 3,051	$ 3,132	$ 3,389	$ 8,630
Capital lease obligations (a)	396	300				
Convertible promissory notes (b)	3,416	5,346	5,346	5,346	5,346	193,932
Total contractual obligations	$ 4,481	$ 8,455	$ 8,397	$ 8,478	$ 8,735	$ 202,562

(a) Includes interest payments.

(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% per annum 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 $28.5 million at maturity date includes $6.2 million of accrued interest payable

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 change of control or a termination of trading of our common stock (each as defined in the indenture for the notes), holders of our notes have the right to require us to repurchase all or any portion of their notes at a price equal to 100% of the principal amount plus accrued and unpaid interest.

FACTORS AFFECTING FUTURE OPERATING RESULTS

Our future operating results could differ materially from the results described in this report due to the risks and uncertainties related to our business, including those discussed below.

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 $29,789,000 for the fiscal year ended December 31, 2003 and as of September 25, 2004, we had an accumulated deficit of approximately $216.6 million. We had a net loss of approximately $34,017,000 for the fiscal year ended December 31, 2002, and, as of December 31, 2002, we had an accumulated deficit of approximately $125,775,000. For the fiscal year ended December 31, 2001, we had a net loss of approximately $10,090,000, and for the fiscal year ended December 31, 2000, we had a net loss of approximately $5,847,000. 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. These costs have exceeded our revenues which to date have been generated principally from collaborations, government grants and sequencing services.

Prior to the merger, GeneSoft Pharmaceuticals, Inc., referred to as Genesoft, had a net loss of approximately $35,813,000 for the fiscal year ended December 31, 2003 and as of December 31, 2003, Genesoft had an accumulated deficit of approximately $91,381,000. Genesoft had a net loss of approximately $25,569,000 for the fiscal year ended December 31, 2002, and, as of December 31, 2002, Genesoft had an accumulated deficit of approximately $55,568,000. For the fiscal year ended December 31, 2001, Genesoft had a net loss of approximately $18,321,000, and for the fiscal year ended December 31, 2000, Genesoft had a net loss of approximately $7,921,000. The losses have resulted primarily from costs incurred in research and development, including Genesoft s clinical trials, and from general and administrative costs associated with Genesoft s operations. These costs have exceeded Genesoft s revenues which to date have been generated principally from funding from the U.S. government.

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 increase in the current year as we will significantly increase our expenditures in the sales and marketing in connection with the commercial launch of FACTIVE tablets. We also plan to continue to expand our research and development and clinical trial activities. In addition, our partners product development efforts which utilize our genomic discoveries are at an early stage and, accordingly, we do not expect our losses to be substantially mitigated by revenues from milestone payments or royalties under those agreements for a number of years, if ever.

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

FACTIVE tablets are currently our only commercial product and we expect they will account for substantially all of our 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 ABECB. The commercial success of FACTIVE tablets will depend upon their acceptance by regulators, physicians, patients and other key decision-makers as a safe, therapeutic and cost-effective alternative to other anti-infectives and other products used, or currently being developed, to treat CAP and ABECB. The commercial success of FACTIVE tablets will also depend on adequate distribution in wholesalers and pharmacies. If FACTIVE tablets 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 ABECB. 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 in the next three years. 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 their 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 will need to raise additional funds in the future.

In connection with the merger with Genesoft, we raised approximately $80,907,000, after deducting placement agents fees and estimated offering expenses payable by us. We believe that these funds, along with the proceeds from the offering of convertible notes that closed during the second quarter of this fiscal year, our pre-existing cash and marketable securities, borrowings under equipment financing arrangements and anticipated cash flows from operations will be sufficient to support our current plans for at least 27 months. We will need to raise additional capital in the future to fund our operations and may seek to raise this capital from time to time, depending upon our performance and market factors. In particular, we expect we will raise additional funds to support our sales and marketing activities, and fund clinical trials and other research and development activities. 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 biotechnology companies and the progress of the FACTIVE and Ramoplanin commercial and clinical development 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 and our other product candidates.

FACTIVE tablets are our first FDA approved product. To date, we have very limited marketing and sales experience. We have built a sales and marketing force to launch FACTIVE and are currently in the process of expanding our sales organization from 106 sales representatives to 250 representatives, and our other product candidates, including Ramoplanin. We will need to continue to expand and retain our sales and marketing staff to successfully commercialize FACTIVE tablets. The development of these marketing and sales capabilities will require significant expenditures, management resources and time. We may be unable to build and maintain such a large enough sales force or the cost of establishing such a sales force may exceed any product revenues, or our marketing and sales efforts may be unsuccessful. In addition, we may be unable to meet our goal of finding a suitable sales and marketing partner for FACTIVE tablets in 2005. Failure to successfully establish and maintain sales and marketing capabilities in a timely and regulatory compliant manner or to find suitable sales and marketing partners may prevent us from successfully commercializing FACTIVE tablets which would materially adversely affect our business and results of operations.

We will depend on third parties to manufacture our product candidates, including FACTIVE tablets and Ramoplanin.

We will not have the internal capability to manufacture commercial quantities of pharmaceutical products under the FDA s current Good Manufacturing Practices. We are party to an agreement with LG Life Sciences to manufacture bulk quantities of FACTIVE. We have also entered into an agreement with Biosearch (which merged with Versicor Inc. in March 2003 and subsequently changed its name to Vicuron Pharmaceuticals Inc.) to manufacture bulk quantities of Ramoplanin, and we expect to

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enter into similar agreements with third parties for the manufacture of future product candidates. Although the LG Life Sciences facilities have previously been inspected by the FDA, they had not been actively manufacturing product for 32 months until their re-start of activity in October 2003. Future inspections may find deficiencies in the facilities or processes that may delay or prevent the manufacture or sale of FACTIVE tablets.

LG Life Sciences is obligated to provide us with finished product until the termination or expiration of its existing agreement with SB Pharmco Puerto Rico, Inc., or SB Pharmco, which provides for the supply of finished FACTIVE product by SB Pharmco. The term of this agreement ended on June 30, 2004, but was extended by LG Life Sciences to complete existing orders and product commitments already in the supply chain pipeline. We have initiated the technology transfer process with a new provider of finished products, which will assume these responsibilities for subsequent periods. We estimate that a new provider of finished FACTIVE tablets will obtain the necessary FDA qualifications by the second half of fiscal 2005. We expect to obtain quantities of FACTIVE tablets from SB Pharmco that will provide us with sufficient inventory until the new provider can be qualified. If we are unable to obtain the FDA approvals necessary to qualify a new provider by the time that our supply of finished FACTIVE tablets to be received from SB Pharmco is exhausted, our supply of FACTIVE product would be interrupted and our business may be materially adversely affected. In addition, we cannot assure you that SB Pharmco or any new secondary manufacturer will be able to avoid batch failures or other production delays which could cause our supply of FACTIVE tablets to be interrupted.

We cannot be certain that LG Life Sciences, Vicuron or future manufacturers will be able to deliver commercial quantities of product candidates to us or that such deliveries will be made on a timely basis. Currently, the only source of supply for FACTIVE bulk drug product is LG Life Sciences facility in South Korea, and if such facility were damaged or otherwise unavailable, we would incur substantial costs and delay in the commercialization of FACTIVE tablets. 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 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 clinical trials for the treatment of acute bacterial sinusitis, or ABS, with FACTIVE tablets have previously been completed, there is no assurance that the FDA or other regulatory agencies will find the results of these trials to be sufficient to approve the sale of FACTIVE for ABS. We may be unable to obtain the necessary regulatory approvals to market FACTIVE for ABS or we may need to conduct additional clinical trials in order to market FACTIVE for this indication. We are also developing an intravenous formulation of FACTIVE, which will be subject to a Phase I bioequivalence study in the coming months. 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,

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Monaco, San Marino and Vatican City. As additional European countries are admitted as members of the European Union. It could negatively impact the profits from our sales of FACTIVE tablets. If, for example, LG Life Sciences were to sell FACTIVE or license a third party to sell FACTIVE in such countries after they are admitted to the European Union, our ability to maintain our projected profit margins based on sales in the territories covered by the LG Life Sciences license agreement may be adversely affected because customers in our territory may purchase FACTIVE from neighboring countries in the European Union and our ability to prohibit such purchases may be limited under European Union antitrust restrictions.

Failure to secure distribution partners 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 FACTIVE 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 FACTIVE, Ramoplanin or any additional products we may acquire on terms which we deem favorable, our results of operations would be materially adversely affected.

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, will need to complete a Phase IV post-approval clinical trial in compliance with FDA requirements pursuant to the product s approval. 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. On August 10, 2004, the Company announced preliminary results of its Phase II trial of Ramoplanin for the treatment of Clostridium difficile-associated diarrhea (CDAD). We are seeking a Special Protocol Assessment (SPA) from the FDA for a Phase III trial for CDAD in 2005, but there can be no assurance that the FDA will grant the SPA. In July 2004, the Company decided to close enrollment on its Phase III clinical trial of Ramoplanin for the prevention of

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bloodstream infections caused by vancomycin-resistant enterococci (VRE) prior to completion of the trial. The Company intends to analyze the results of the VRE trial and make a determination at a later date as to any future course of action for this indication. 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.

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;
- 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, but commercialized by Schering-Plouch in the United States under a recently announced marketing alliance;

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

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

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In addition, Ketek®, a new ketolide antibiotic from Aventis Pharmaceuticals, was recently launched in the United States and is being marketed in Europe. 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 2010. 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.

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 Vancocin® (vancomycin), a product marketed by ViroPharma, and metronidazole, a generic product for treatment of this indication. We are also aware of at least three companies with products in development for the treatment of CDAD Geltex/Genzyme in Phase II; 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. In July 2004, in order to devote resources to other development programs, the Company decided to close enrollment on its Phase III clinical trial of Ramoplanin for the prevention of bloodstream infections caused by vancomycin-resistant enterococci (VRE) prior to completion of the trial. The Company intends to analyze the results of the VRE trial and make a determination at a later date as to any future course of action for this indication. We have no knowledge of any product currently approved by the FDA for this indication, nor are we aware of any product candidate currently in clinical trials for this indication. It is possible that competition exists without our knowledge and that current discovery and preclinical efforts are ongoing for this indication.

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 AstraZeneca, 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.

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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.

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

We will be highly dependent on the principal members of our senior management and key scientific and technical personnel. The loss of any of our personnel could have a material adverse effect on our ability to achieve our goals. We currently maintain employment agreements with the following senior officers: Steven M. Rauscher, President and Chief Executive Officer; Stephen Cohen, Senior Vice President and Chief Financial Officer; and Gary Patou, M.D., Executive Vice President, Chief Medical Officer. The term of each employment agreement continues until it is terminated by the officer or us, except for Dr. Patou s agreement which runs through January 1, 2005, after which he becomes a consultant for one year. 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 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 57 issued U.S. patents, approximately 90 pending U.S. patent applications, 67 issued foreign patents and approximately 154 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;

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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 a crystal form of 7-(3-aminomethyl-4-methoxyiminopyrrolidin-1-yl)-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1,8-naphthyridine-3-carboxylic acid methanesulfonate; licensed from LG Life Science; expiring March 20, 2018.

While it is difficult to assess the value of our intellectual property portfolio, the patents named above may provide a competitive advantage in certain instances in the pathogen and anti-infective field by requiring others to obtain a license from us if they wish to produce competing products. However, there is no assurance that any of these patents, if challenged, will be found to be enforceable or that any of these patents will provide us with a competitive advantage.

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 14 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 their

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use for the prophylaxis and treatment of bacterial infections. The U.S. patents are currently set to expire at various dates, ranging from 2015, in the case of the principal patents relating to FACTIVE, to 2019. We have filed patent term extension applications, covering the regulatory review process, for the principal patents. If granted, these extensions would extend the exclusivity period through 2017.

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 468 has been reexamined with relatively minor modifications to the claims and confirmed patentable over the submitted references. The reexamination of Patent 944 is currently pending. If the PTO does not confirm the claims in this patent as patentable, our patent protection with respect to FACTIVE in the U.S. may be weakened.

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 or may take longer than expected to result in issued patents;
- the claims of any patents which are issued may be limited from those in the patent applications and may not provide meaningful protection;
- we may not be able to develop additional proprietary technologies that are patentable;
- the patents licensed or issued to us or our partners may not provide a competitive advantage;
- other companies may challenge patents licensed or issued to us or our partners;
- patents issued to other companies may harm our ability to do business; 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 will bear substantial responsibilities under our license agreements for FACTIVE and Ramoplanin, 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 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

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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.

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 they intend to seek to terminate the License and Supply Agreement between Vicuron and Oscient and reacquire rights to Ramoplanin. In their 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 their 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 will address this issue with Vicuron. There is no assurance 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 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.

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 biotechnology 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

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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 an 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.

We may not realize all of the anticipated benefits of the merger with Genesoft.

The success of our merger with Genesoft will depend, in part, on our ability to realize the anticipated synergies, cost savings and growth opportunities from integrating our business with the former business of Genesoft. Our success in realizing these benefits and the timing of this realization depends upon the successful integration of the former operations of Genesoft. The full integration of two independent companies, especially when one company is located on the West Coast and the other on the East Coast, is a complex, costly and time-consuming process. The difficulties of combining the operations of the companies and realizing the expected benefits of the merger include, among others:

- coordinating commercial and clinical development initiatives and staffs for FACTIVE and Ramoplanin;
- raising sufficient capital to fund the significant expenditures that are needed to launch and successfully commercialize FACTIVE and the further clinical development of Ramoplanin;
- retaining key employees;
- consolidating research and development operations;
- consolidating corporate and administrative infrastructures and physical plant;

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integrating and managing the technology of two companies; and

minimizing the diversion of management s attention from ongoing business concerns.

We cannot assure you that we will realize the full benefits anticipated by us to result from the merger. In addition, we may not have sufficient capital to fully implement our strategies following the merger which may cause a delay in the launch of FACTIVE tablets and could further prevent us from realizing the anticipated benefits of the merger.

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

We have a substantial level of debt. As of September 25, 2004, after giving effect to the issuance and sale of the convertible notes during the second quarter of this fiscal year, 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, 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. If we succeed in bringing FACTIVE tablets, Ramoplanin or other products in the future to market, 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, 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, Ramoplanin or any of our future products will be added to payers formularies, whether our products will have

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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 FACTIVE tablets, Ramoplanin or future products.

Wholesalers, Pharmacies and Hospitals may not provide adequate distribution for our Products.

Our ability to commercialize FACTIVE tablets, Ramoplanin and our future 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 commercial launch of FACTIVE and our anticipated revenues and results of operations could be adversely affected.

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

The use of any of our product candidates in clinical trials, and the sale of any approved products, might expose us to product liability claims. We currently maintain, and we expect that we will continue to maintain, product liability insurance coverage in the amount of $10 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 launch and commercialize FACTIVE tablets;

the revenues that we may derive from the sale of FACTIVE tablets, 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 September 25, 2004 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 $1.03. 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.

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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 commercial launch of FACTIVE tablets;
- the level of acceptance by physicians and third party payors of FACTIVE;
- 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.

Certain of our financial statements have been audited by Arthur Andersen LLP, and the ability to recover damages from Arthur Andersen may be limited.

Prior to June 24, 2002, Arthur Andersen LLP served as our independent public accountants. Our inability to obtain the consent of Arthur Andersen to include its report on certain financial statements audited by Arthur Andersen may limit your recovery against Arthur Andersen. SEC rules require us to include or incorporate by reference certain historical financial statements for the years ended December 31, 2001 and 2000 that were audited by Arthur Andersen. As a result of the well-publicized events concerning Arthur Andersen, we have not been able to obtain the consent of Arthur Andersen to the inclusion of its audit report in financial statements audited by them and will not be able to obtain Arthur Andersen s consent in the future. The absence of this consent may limit any recovery to which you might be entitled against Arthur Andersen. It is also likely that these events concerning Arthur Andersen would materially adversely affect its ability to satisfy any claims we might have arising from its provision of auditing and other services to us.

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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, 2003, and in Exhibit 99.1 to this Report on Form 10-Q. Our Annual Report on Form 10-K was filed with the Securities and Exchange Commission on March 5, 2004. There have been no material changes in the first nine months of 2004 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 third 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.

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PART II

Item 1. ***Legal Proceedings***

None

Item 2. ***Changes in Securities***

None

Item 3. ***Defaults Upon Senior Securities***

None

Item 4. ***Submission of Matters to a Vote of Security Holders***

None

Item 5. ***Other Information***

None

Item 6. ***Exhibits and Reports on Form 8-K***

a) Exhibits:

Exhibit No.	Description

31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) under the Securities Exchange Act of 1934, as amended.
32.1	Certification pursuant to Section 1350, Chapter 63 of Title 18, United States Code, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 of the Company s Chief Executive Officer.
32.2	Certification pursuant to Section 1350, Chapter 63 of Title 18, United States Code, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 of the Company s Chief Financial Officer.

b) Reports on Form 8-K

The following Reports on Form 8-K were filed or furnished to the Commission:

1) Report on Form 8-K filed on August 9, 2004 to report that the Company issued a press release announcing its financial results for its first fiscal quarter ended June 26, 2004.

2) Report on Form 8-K filed on August 10, 2004 to report that the Company issued a press release announcing the completion of its Phase II clinical trial of Ramoplanin for the treatment of *Clostridium difficile*-associated diarrhea.

3) Report on Form 8-K filed on August 12, 2004 to report that the Company s Chief Medical Officer entered into a written stock trading plan in accordance with Rule 10b5-1 under the Securities Exchange Act of 1934.

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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)

November 9, 2004

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OSCIENT PHARMACEUTICALS CORPORATION AND SUBSIDIARIES

EXHIBIT INDEX

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32.2	Certification pursuant to Section 1350, Chapter 63 of Title 18, United States Code, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 of the Company s Chief Financial Officer.

The above referenced exhibits are filed herewith and are referred to and incorporated herein by reference to such filings.