

OSCIENT PHARMACEUTICALS CORP

Form 10-Q

August 10, 2004

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# SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

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## FORM 10-Q

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

For the Quarterly Period Ended: June 26, 2004

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

Commission File No: 0-10824

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# OSCIENT PHARMACEUTICALS CORPORATION

(Exact name of registrant as specified in its charter)

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MASSACHUSETTS  
(State or other jurisdiction of

incorporation or organization)

04-2297484  
(I.R.S. Employer

Identification no.)

**100 BEAVER STREET**

**WALTHAM, MASSACHUSETTS 02453**

**(Address of principal executive offices) (Zip code)**

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

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

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

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

**COMMON STOCK  
\$0.10 PAR VALUE**

**74,891,931 Shares  
Outstanding August 4, 2004**

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**OSCIENT PHARMACEUTICALS CORPORATION AND SUBSIDIARIES**

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	December 31, 2003	June 26, 2004
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 20,969,292	\$ 87,266,332
Marketable securities (held-to-maturity)	4,595,740	97,333,401
Marketable securities (available-for-sale)	3,100,000	
Interest receivable	138,189	1,863,959
Accounts receivable	257,389	359,358
Unbilled costs and fees	78,899	734,103
Inventory		4,912,416
Prepaid expenses and other current assets	41,953	2,927,160
	<u>29,181,462</u>	<u>195,396,729</u>
Total Current Assets		
Property and Equipment, at cost:		
Laboratory and scientific equipment	12,573,855	12,747,715
Leasehold improvements	7,516,159	7,551,702
Equipment and furniture	1,240,682	1,318,891
	<u>21,330,696</u>	<u>21,618,308</u>
Less Accumulated depreciation	18,009,495	18,445,381
	<u>3,321,201</u>	<u>3,172,927</u>
Restricted cash		18,792,760
Long-term marketable securities (held-to-maturity)		22,698,377
Notes receivable	6,238,219	
Other assets	1,775,433	5,680,169
Intangible assets		72,805,050
Goodwill		55,610,085
	<u>\$ 40,516,315</u>	<u>\$ 374,156,097</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current Liabilities:		
Current maturities of long-term obligations	1,166,667	\$ 1,109,127
Accounts payable	1,523,633	3,818,493
Accrued expenses	3,483,308	6,998,920
Accrued facilities impairment charge		2,384,012
Clinical trial expense accrual	3,652,604	5,483,171
Deferred revenue	458,333	
	<u>10,284,545</u>	<u>19,793,723</u>
Total Current Liabilities		
Long-term Liabilities:		
Long-term obligations, net of current maturities	291,666	175,059,647
Accrued facilities impairment charge		13,509,399
Other long-term liabilities		603,052
Shareholders' Equity:		

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Common stock and additional paid-in capital	185,875,163	363,171,908
Accumulated deficit	(155,564,152)	(192,309,812)
Other shareholders' equity	(370,907)	(5,671,820)
	<u>                    </u>	<u>                    </u>
Total Shareholders' Equity	29,940,104	165,190,276
	<u>                    </u>	<u>                    </u>
	\$ 40,516,315	\$ 374,156,097
	<u>                    </u>	<u>                    </u>

See Notes to Consolidated Condensed Financial Statements

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

	Thirteen Week Period Ended		Twenty-Six Week Period Ended	
	June 28, 2003	June 26, 2004	June 28, 2003	June 26, 2004
<b>Revenues:</b>				
Biopharmaceutical	\$ 1,457,057	\$ 709,775	\$ 2,911,414	\$ 2,370,920
Genomics services	252,974		1,537,667	100,000
<b>Total revenues</b>	<b>1,710,031</b>	<b>709,775</b>	<b>4,449,081</b>	<b>2,470,920</b>
<b>Costs and Expenses:</b>				
Cost of services			1,902,561	
Research and development (1)	4,337,911	6,165,948	11,053,351	11,360,781
Write-off of in-process technology at merger				11,704,396
Restructuring charge	3,990,748		3,990,748	98,649
Convertible debt retirement expense	5,527,833		5,527,833	
Stock based compensation	179,275	1,881,717	226,685	2,446,296
Selling, general and administrative (1)	1,489,522	9,266,010	3,666,476	12,891,001
<b>Total costs and expenses</b>	<b>15,525,289</b>	<b>17,313,675</b>	<b>26,367,654</b>	<b>38,501,123</b>
<b>Loss from operations</b>	<b>(13,815,258)</b>	<b>(16,603,900)</b>	<b>(21,918,573)</b>	<b>(36,030,203)</b>
<b>Other Income (Expense):</b>				
Interest income	147,582	497,808	379,661	689,865
Interest expense	(261,872)	(1,245,073)	(972,324)	(1,540,885)
Gain (loss) on sale of fixed assets	(2,157)	84,829	(132,158)	126,513
Other income				9,050
<b>Net other income (expense)</b>	<b>(116,447)</b>	<b>(662,436)</b>	<b>(724,821)</b>	<b>(715,457)</b>
<b>Net Loss</b>	<b>\$ (13,931,705)</b>	<b>\$ (17,266,336)</b>	<b>\$ (22,643,394)</b>	<b>\$ (36,745,660)</b>
<b>Net Loss per Common Share:</b>				
Basic and diluted	\$ (0.58)	\$ (0.23)	\$ (0.95)	\$ (0.56)
<b>Weighted Average Common Shares Outstanding:</b>				
Basic and diluted	24,192,302	74,325,687	23,893,661	65,237,885
(1) Excludes non-cash stock based compensation as follows:				
Research and development	\$ 179,275	\$ 1,661,619	\$ 226,685	\$ 2,098,655
Selling, general and administrative	179,275	220,098	226,685	347,641
	\$ 179,275	\$ 1,881,717	\$ 226,685	\$ 2,446,296

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See Notes to Consolidated Condensed Financial Statements.





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Net cash provided by (used in) financing activities	(11,443,173)	229,021,890
<b>Net Increase (Decrease) in Cash and Cash Equivalents</b>	<b>(945,083)</b>	<b>66,297,040</b>
<b>Cash and Cash Equivalents, beginning of period</b>	<b>14,228,507</b>	<b>20,969,292</b>
<b>Cash and Cash Equivalents, end of period</b>	<b>\$ 13,283,424</b>	<b>\$ 87,266,332</b>
<b>Supplemental Disclosure of Cash Flow Information:</b>		
Interest paid during period	\$ 544,847	\$ 41,518
Income tax paid during period	\$ 12,213	\$ 17,939
<b>Supplemental Disclosure of Non-cash Investing and Financing Activities:</b>		
Unrealized gain on marketable securities	\$ 153,451	\$
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 Condensed Financial Statements

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**OSCIENT PHARMACEUTICALS CORPORATION AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS**

**(unaudited)**

**(1) BASIS OF PRESENTATION**

These consolidated condensed 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 condensed 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 period. 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 condensed 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. The Company's product portfolio is now 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 April 13, 2004, the Company changed its name from Genome Therapeutics Corp. to Oscient Pharmaceuticals Corporation.

In addition, the Company is developing a novel antibiotic candidate, Ramoplanin, which is currently in clinical trials for the prevention and 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 and discussions with the FDA, the Company plans to commence a Phase III trial for CDAD by the end of this year. In July 2004, in order to devote resources to the CDAD trial, 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. We also have 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 our genomics drug discovery expertise. It is no longer our focus to pursue gene discovery or additional partnerships of this type.

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The Company's strategic goal is to supplement its existing product and clinical candidates with additional therapeutic opportunities, either through in-licensing or through mergers with, and acquisitions of, appropriate companies. The Company merged with Genesoft not only to supplement our product pipeline, but also to gain access to leading industry experts that will play a critical role in future product and business development efforts.

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

### *(a) Principles of Consolidation*

The accompanying consolidated condensed 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.

### *(b) Revenue Recognition*

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Biopharmaceutical revenues consist 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 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 probable. 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.

Amounts received for license fees are deferred and recognized ratably over the performance period in accordance with Staff Accounting Bulletin (SAB) No. 104, Revenue Recognition. Milestone payments will be 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. Unbilled costs and fees represent revenue recognized prior to billing. Deferred revenue represents amounts received prior to revenue recognition.

*(c) Clinical Trial Expense Accrual*

The Company's clinical development trials related to Ramoplanin 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 June 26, 2004. However, readers should be cautioned that the possibility exists that the timing or cost of the Ramoplanin 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.

For the clinical development of Ramoplanin, the Company recorded expenses of approximately \$4,073,000, and \$6,688,000 for the twenty-six week periods ended June 28, 2003 and June 26, 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.

	<u>Estimated Useful Life</u>
Laboratory Equipment	5 Years
Computer Equipment & Licenses	3 Years

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Office Equipment	5 Years
Furniture & Fixtures	5 Years

Depreciation expense was approximately \$1,640,000 and \$640,000 for the twenty-six week periods ended June 28, 2003 and June 26, 2004, respectively.

### *(e) Inventory*

Inventory is stated at the lower of cost (first in, first out) or market (net realizable value). As of June 26, 2004, inventory consists entirely of finished FACTIVE tablets for sample and commercial sale related to the anticipated product launch of FACTIVE in September 2004.

### *(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

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share totaled 5,055,045 and 38,005,371 shares of the Company's common stock during twenty-six week periods ended June 28, 2003 and June 26, 2004, respectively.

*(g) Concentration of Credit Risk*

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

The 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				
		A	B	C	D	E
Thirteen-week period ended:						
June 28, 2003	4		11%	20%	16%	51%
June 26, 2004	1	88%				
Twenty-six week period ended:						
June 28, 2003	4	22%		16%	12%	37%
June 26, 2004	2	52%				41%

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:

	Percentage of Total Accounts Receivable				
	A	B	C	D	E
As of:					
December 31, 2003	21%	64%			

*(h) Use of Estimates*

The preparation of consolidated condensed financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated condensed financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

*(i) 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.

*(j) Reclassifications*

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

*(k) Comprehensive Income (Loss)*

The Company follows the provisions of SFAS No. 130, Reporting Comprehensive Income. SFAS No. 130 requires disclosure of all components of comprehensive income (loss) on an annual and interim basis. Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner

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sources. Historically, other comprehensive income had included net loss and change in unrealized gains and losses in marketable securities. For the twenty-six week period ended June 28, 2003, the Company recorded approximately \$153,000 to comprehensive income related to the increase in fair market value of common shares. For the period ended June 26, 2004, net loss equaled comprehensive loss.

*(l) Segment Reporting*

The Company follows the provisions of SFAS No. 131, Disclosures about Segments of an Enterprise and Related Information. SFAS No. 131 establishes standards for reporting information regarding operating segments in annual financial statements and requires selected information for those segments to be presented in interim financial reports issued to stockholders. SFAS No. 131 also establishes standards for related disclosures about products and services and geographic areas. Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions as to how to allocate resources and assess performance. The Company's chief decision makers, as defined under SFAS No. 131, are the chief executive officer and chief financial officer. 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).

	<u>Genomics Services</u>	<u>Biopharmaceutical</u>	<u>Total</u>
Twenty-six week period ended June 28, 2003			
Revenues	\$ 1,537,667	\$ 2,911,414	\$ 4,449,081
Gross profit (loss)	(364,894)	552,809	187,915
Company-funded research & development costs		8,694,746	8,694,746
Twenty-six week period ended June 26, 2004			
Revenues	\$ 100,000	\$ 2,370,920	\$ 2,470,920
Gross profit	100,000	364,186	464,186
Company-funded research & development costs		9,354,047	9,354,047

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, we only receive 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.

*(m) 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.

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 June 26, 2004, the Company does not believe that any of its long-lived assets, goodwill, and other intangible assets are impaired.



*(n) 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.

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	Twenty-Six Week Period Ended	
	June 28,	June 26,
	2003	2004
Net loss as reported	\$ (22,643,394)	\$ (36,745,660)
Add: Stock-based employee compensation cost, included in the determination of net loss as reported	226,685	2,446,296
Less: Total stock-based compensation expense determined under the fair value method for all employee awards	(1,300,049)	(2,463,967)
<b>Pro forma net loss</b>	<b>\$ (23,716,758)</b>	<b>\$ (36,763,331)</b>
<b>Basis and diluted net loss per share</b>		
As reported	\$ (0.95)	\$ (0.56)
<b>Pro forma</b>	<b>\$ (0.99)</b>	<b>\$ (0.56)</b>

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 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 estimated 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 is currently completing 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 will finalize the purchase price allocation after it completes its analysis of assumed liabilities, and receives other relevant information relating to the acquisition. The final purchase price allocation may be significantly different than the Company's preliminary estimate as presented below:

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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
	<hr/>
Total assets acquired	\$ 152,632
	<hr/>
Liabilities:	
Current Liabilities	\$ 5,199
Long Term Liabilities	22,310
Accrued Facility Costs	16,887
	<hr/>
Total Liabilities acquired	\$ 44,396
Net Assets acquired	\$ 108,236
	<hr/>

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 of between 15% to 22%. The valuation of purchased intangible assets include 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

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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.

At the time of acquisition, management approved a plan to integrate certain Genesoft facilities into existing operations. Included in the purchase price allocation is 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 June 26, 2004, the Company paid \$688,000 against the accrual for severance-related costs and \$993,000 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 \$2,320,000 in amortization of deferred compensation through June 26, 2004 in connection with the merger.

*Supplemental Pro Forma Information:*

The unaudited pro forma combined condensed statements of operations for the twenty-six week period ended June 26, 2004 and June 28, 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. The allocation of the purchase price is preliminary. Final amounts could differ from those reflected in the pro forma statements of operations.

	Twenty-Six Weeks Ended			
	(In thousands, except per share data)			
	June 26, 2004 (Actual)	June 26, 2004 (Pro forma)	June 28, 2003 (Actual)	June 28, 2003 (Pro forma)
Revenue	\$ 2,471	\$ 2,904	\$ 4,449	\$ 7,354
Total costs and expenses	39,217	42,110	27,092	50,683
Net loss	\$ (36,746)	\$ (39,206)	\$ (22,643)	\$ (43,329)
Weighted average number of shares basic and diluted	65,238	65,238	23,894	35,289
Net loss per share	\$ (0.56)	\$ (0.60)	\$ (0.95)	\$ (1.23)

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The pro-forma adjustments include additional amortization expense of \$623 for the twenty-six week period ended June 26, 2004 and \$3,738 for the twenty-six week period ended June 28, 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 drug discovery programs under its biopharmaceutical operating segment. Under this plan, the Company eliminated 44 full-time positions and recorded a restructuring charge of approximately \$5.3 million in 2003 and \$99,000 for the twenty-six week period ended June 26, 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

#### Twenty-Six Week Period Ended June 26, 2004

	Balance at December 31, 2003	Charges	Cash Payments	Asset Impairment	Stock Option Compensation	Balance at June 26, 2004
Termination benefits	\$ 612,241	\$ 98,649	\$ (319,845)	\$	\$	\$ 391,045

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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 will be paid out during the first seven 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 \$437,000 through June 26, 2004. At June 26, 2004, the net realized value of the remaining long-lived assets on hand was approximately \$389,000. The Company plans to sell these assets over the next six months.

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

**Twenty-Six Week Period Ended June 26, 2004**

	<b>Balance at December 31, 2003</b>	<b>Liability recorded</b>	<b>Cash Payments</b>	<b>Amortization</b>	<b>Balance at June 26, 2004</b>
Termination benefits	\$	\$ 1,440,685	\$ (687,687)		\$ 752,998
Lease liability		16,886,749	(1,276,773)	283,435	15,893,411
	\$	\$ 18,327,434	\$ (1,964,460)	\$ 283,435	\$ 16,646,409

In addition, the Company recorded interest expense of \$283,435 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 June 26, 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 June 26, 2004, the average maturity of the Company's investments was approximately 6.9 months. Also, at June 26, 2004, the Company had a net unrealized loss of \$238,951, which is the difference between the amortized cost and the fair value of the held-to-maturity investments.

At June 26, 2004, the Company's short-term marketable securities (held-to-maturity) included shares of common stock of Agencourt received in connection with the Asset Purchase Agreement with Agencourt dated March 14, 2003. Such investments are carried at cost which approximates market value.

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At December 31, 2003 and June 26, 2004, the Company's cash and cash equivalents and investments consisted of the following:

	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Loss</u>	<u>Estimated Fair Value</u>
<b>December 31, 2003</b>				
Cash and Cash Equivalents:				
Cash	\$ 17,208,907	\$	\$	\$ 17,208,907
Debt securities	3,760,385	325	(1,335)	3,759,375
<b>Total cash and cash equivalents</b>	<b>\$ 20,969,292</b>	<b>\$ 325</b>	<b>\$ (1,335)</b>	<b>\$ 20,968,282</b>
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
<b>June 26, 2004</b>				
Cash and Cash Equivalents:				
Cash	\$ 79,822,949	\$	\$	\$ 79,822,949
Debt securities	7,443,383	18,892		7,462,275
<b>Total cash and cash equivalents</b>	<b>\$ 87,266,332</b>	<b>\$ 18,892</b>	<b>\$</b>	<b>\$ 87,285,224</b>
Investments (held-to-maturity):				
Short-term marketable securities	\$ 97,333,401	\$ 26,019	\$ (239,803)	\$ 97,119,617
Long-term marketable securities	22,698,377		(44,059)	22,654,318
<b>Total investments (held-to-maturity)</b>	<b>\$ 120,031,778</b>	<b>\$ 26,019</b>	<b>\$ (283,862)</b>	<b>\$ 119,773,935</b>

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### **(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 (1.17% at June 26, 2004) plus 1.50%. The Company is required to maintain certain financial covenants pertaining to minimum cash balances. As of June 26, 2004, \$875,000 was outstanding under the loan agreement.

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.

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. 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. In connection with the issuance, the Company recorded deferred financing costs of \$5,647,999 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 June 26, 2004 consolidated balance sheet. As part of the issuance, the Company filed a shelf registration statement relating to the resale of the notes and the common stock issuable upon conversion.

### **(8) MAJOR RESEARCH AND DEVELOPMENT PROJECTS**

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 our agreement, LG Life Sciences has agreed to supply and the Company is 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 term of this agreement ended on June 30, 2004, but was extended by LG Life Sciences to September 30, 2004 to complete existing orders and product commitments already in the supply chain pipeline. The Company has initiated the technology transfer process with new providers of finished products, one of which will assume these responsibilities for subsequent periods. The Company estimates that it will take 9 to 15 months to qualify a new provider of finished products. The Company expects to obtain quantities of FACTIVE tablets from SB Pharmco that will provide us with

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sufficient inventory until the new provider can be qualified. The Company is also nearly complete in the building of a sales and marketing force in order to permit the launch of FACTIVE tablets in September 2004. Since the launch of FACTIVE tablets is expected to take place 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 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. The Company recently 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). Following further analysis, the Company intends to submit more extensive data from this trial for presentation at one of the fall infectious diseases conferences. Initiation of a Phase III study in this indication is planned for later this year, subject to a full analysis of the data from the Phase II trial and successful planning discussions with the FDA. 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.

## **(9) RESEARCH AND DEVELOPMENT AND ALLIANCES**

Research and development expenses primarily consist of salaries and related expenses for personnel and the cost of materials and supplies used and 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 efforts performed for the Company's alliance partners generally consist of sequencing services and related research activities. 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). The Company is generally compensated for its research and development efforts by its alliance partners on a full-time equivalent basis. Accordingly, the services provided to the Company's alliance partners are generally limited to the performance of a specified number of hours of research. As a result, the Company manages the research efforts related to the Company's alliances through an analysis of direct labor hours and the consideration received on a per full-time equivalent basis.

The Company 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 arrangements separately from its internal research and development programs. During the twenty-six week periods ended June 28, 2003 and June 26, 2004, the Company incurred expenditures of approximately \$2,359,000 and \$2,007,000, respectively, related to its alliances.

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. Potential revenues (exclusive of royalty payments earned upon the successful commercialization of products) earned by the Company generally included an upfront license fee, sponsored /contract research payments and research and development and regulatory approval milestone payments. Those future payments are earned primarily through the achievement of research, development and regulatory approval milestones. The Company's ability to earn those future milestone payments depends primarily upon whether our alliance partner identifies any compounds, through high-throughput screening and lead optimization, that warrant clinical

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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 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 June 26, 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 \$1,633,000 and \$1,013,000, in revenue during the twenty-six week periods ended June 28, 2003 and June 26, 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**

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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 forward-looking statements. All forward-looking statements involve certain risks, estimates, assumptions, and uncertainties with respect to future revenues, cash flows, expenses and the cost of capital, among other things.

Some of the important risk factors that could cause our actual results to differ materially from those expressed in our forward-looking statements 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 and (iii) lack of acceptance of the product by physicians, patients and third party payors;

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 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 based on our genomics information; and

our dependence on key personnel.

In addition to the risk factors set forth above, you should consider the risks set forth in Exhibit 99.1 to this Report on Form 10-Q and those set forth in other filings with the Securities and Exchange Commission. We undertake no obligation to revise the forward-looking statements included in this Report to reflect any future events or circumstances.

## **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 now 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. For the near term, we intend to focus our efforts on the launch of commercial sales of FACTIVE tablets for these indications. We anticipate the launch of FACTIVE will occur in September of 2004.

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In addition, we are developing a novel investigational antibiotic candidate, Ramoplanin, which is currently in clinical trials for the prevention and 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 and discussions with the FDA, we plan to commence a Phase III trial for CDAD by the end of this year. In July 2004, in order to devote resources to the CDAD trial, 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. 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 focused 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.

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 product discovery 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 anticipate that we will also generate revenue from the sale of FACTIVE tablets following its launch in September of 2004.

We have incurred significant operating losses since our inception. As of June 26, 2004, we had an accumulated deficit of approximately \$192.3 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.

## **Major Research and Development Projects**

### *FACTIVE (gemifloxacin mesylate) Tablets*

Our ongoing clinical trials and other development activities for the FACTIVE product for the twenty-six week period ended June 26, 2004 totaled approximately \$1,062,000. 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 gemifloxacin in such country. In the United States, the last of the currently issued patents expires in 2019. The product was approved for sale in the United States in April 2003 for the treatment of acute bacterial exacerbation of chronic bronchitis and community-acquired pneumonia of

mild to moderate severity.

Under the terms of 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 September 30, 2004 to complete existing orders and product commitments already in the supply chain pipeline. The Company has initiated the technology transfer process with new providers of finished products, one of which will assume these responsibilities for subsequent periods. We estimate that it will take 9 to 15 months to qualify a new provider of finished products. 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. We are also in the process of building a sales and marketing force in order to permit the launch of FACTIVE tablets in September of 2004. Since the launch of FACTIVE tablets is expected to take place in September of 2004, we do not expect sales of FACTIVE tablets to have a significant impact on our operating results in 2004.

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

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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 is expected to commence proximate to the product launch in the U.S.

Our ability to successfully launch FACTIVE tablets in September of 2004 is subject to a number of risks, including the results of the Phase IV trial described above, 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 launch FACTIVE tablets in September of 2004, our operations, financial position and liquidity would be negatively affected to a significant degree.

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, arena were completed. We are in the process of discussing with the FDA activities related to an anticipated filing of a NDA for this indication in 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.

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.

### *Ramoplanin*

Our ongoing clinical trials and other development activities for Ramoplanin has constituted our most significant research and development project comprising 37% and 58% of total research and development expenditures for twenty-six week periods ended June 28, 2003 and June 26, 2004, respectively. Expenses for Ramoplanin comprise 48% 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, the Company plans to commence a Phase III trial for CDAD by the end of this year. In July 2004, in order to devote resources to the CDAD trial, 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 made a determination at a later date as to any future course of action for this indication.



In addition, as of June 26, 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. 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.

*Biopharmaceutical Alliances*

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Another major research and development focus of ours has been the support we have 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 18% of total research and development expenses for the twenty-six week periods ended June 28, 2003 and June 26, 2004, respectively. Research and development expense to support our alliances was 34% of the total research and development expense from January 1, 1995 through June 26, 2004. The research phase of our alliances have ended as of June 26, 2004.

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:

<b>Biopharmaceutical Alliances</b>	<b>Goal</b>	<b>Status</b>
AstraZeneca, August 1995	Develop pharmaceutical, vaccine and diagnostic products effective against gastrointestinal infections or any other disease caused by <i>Helicobacter pylori</i> ( <i>H. pylori</i> ).	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 <i>Staphylococcus aureus</i> ( <i>S. aureus</i> ) 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 <i>in vitro</i> 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.

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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.

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### *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 \$5.6 million through June 26, 2004. This charge consisted of a reduction in work force and includes associated severance costs, outplacement services and a non-cash charge for the acceleration of vesting of previously granted stock options, as well as impairment charges related to the value of laboratory and computer equipment no longer used in operations.

As a combined category, these research efforts represented 42% and 15% of total research and development expenses for the twenty-six week periods ended June 28, 2003 and June 26, 2004, respectively. These efforts comprised 46% of the total research and development expense during January 1, 1995 through June 26, 2004.

Our current portfolio of internal drug discovery programs focuses on bacterial infections and the growing need to develop antibacterial compounds with novel mechanisms of action. Our research program is now focused on the optimization of second-generation, orally-available PDF inhibitors with the potential to target the broader community-based antibiotic market. Several compounds have been identified with improved properties, including good activity against *H. influenzae*. As a result of our strategic shift away from early stage discovery, it is our intent to form a partnership with another drug company to provide the funding and the expertise for the optimization effort for the PDF inhibitor program. Additionally, as a result of our previous internal drug discovery efforts, we have identified two novel chemical series ready to enter the lead optimization phase with a partner. These two lead series are aimed at novel, broad-spectrum targets and have the potential to be new classes of antibacterials. In addition to these lead compounds, we have identified hit series on six additional antimicrobial screens.

Our ability to obtain our goals for our previously funded internal drug discovery research programs is subject to numerous risks including our inability to find strategic partners in an increasingly competitive environment for strategic alliances. Even if we find strategic partners for these programs, the partners may not be successful in developing these discoveries further. Due to all of these uncertainties, we can provide no assurance that we will ever receive any material cash inflows from these programs.

### **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.

### *Revenue Recognition*

Biopharmaceutical revenues consist of license fees and contract research and milestone payments from alliances with pharmaceutical companies. Genomics services revenues consist 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 probable. 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 in accordance with Staff Accounting Bulletin (SAB) No. 104, Revenue Recognition. Milestone payments will be 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.

*Clinical Trial Expense Accrual*

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Our clinical development trials related to Ramoplanin 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 June 26, 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 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. All actual and estimated costs to complete the Phase III trial are reflected in the accrual at June 26, 2004. However, readers should be cautioned that the possibility exists that the timing or cost of the Ramoplanin 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 June 28, 2003 and June 26, 2004***

#### *Revenues*

Total revenues decreased 58% from \$1,710,000 for the thirteen-week period ended June 28, 2003 to \$710,000 for the thirteen-week period ended June 26, 2004.

Biopharmaceutical revenues decreased 51% from \$1,457,000 for the thirteen-week period ended June 28, 2003 to \$710,000 for the thirteen-week period ended June 26, 2004, primarily due to the reduction of revenues from alliances due to the conclusion of research agreements, partially offset by two new government grants with NIH which started in August 2003 along with Genesoft's government grants with DARPA.

Revenues from Genomics Services decreased 100% from \$253,000 for the thirteen-week period ended June 28, 2003 to \$0 for the thirteen-week period ended June 26, 2004 primarily due to 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 our anticipated launch of the sale of our FACTIVE tablets in September of 2004.

#### *Costs and Expenses*

Total costs and expenses increased 12% from \$15,525,000 for the thirteen-week period ended June 28, 2003 to \$17,314,000 for the thirteen-week period ended June 26, 2004.

Research and development expenses include internal research and development expenses, research funded pursuant to arrangements with our 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 44% from \$4,338,000 for the thirteen-week period ended June 28, 2003 to \$6,166,000 for the thirteen-week period ended June 26, 2004. This increase was primarily due to increased expenses relating to our clinical development trials related to Ramoplanin and FACTIVE intravenous formulation.

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 \$3,991,000 for the thirteen-week period ended June 26, 2003, of which \$291,000 was related to severance costs and outplacement services and approximately \$3,700,000 of impairment charges related to the value of laboratory and computer equipment no longer used in operations.

During the thirteen-week period ended June 28, 2003, we also recorded a one-time charge to convertible debt retirement expense of approximately \$5,528,000 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 \$562,000 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.

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Stock-based compensation increased 951% from \$179,000 for the thirteen-week period ended June 28, 2003 to \$1,882,000 for the thirteen-week period ended June 26, 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.

Selling, general and administrative expenses increased 522% from \$1,490,000 for the thirteen-week period ended June 28, 2003 to \$9,266,000 for the thirteen-week period ended June 26, 2004. The increases in selling, general and administrative expenses is due to increased sales and marketing personnel and related costs of approximately \$5,354,000, increased general and administrative personnel, hiring and consulting costs of approximately \$1,863,000, and increased legal and patent costs of approximately \$558,000 to support the launch of FACTIVE in September 2004. Selling, general and administrative expenses are expected to increase in the foreseeable future as we continue to expand our commercialization efforts related to FACTIVE.

### *Other Income and Expense*

Interest income increased 237% from \$148,000 for the thirteen-week period ended June 28, 2003 to \$498,000 for the thirteen-week period ended June 26, 2004 reflecting higher cash balances due to the convertible debt proceeds received in the second quarter of 2004 as well as higher interest rate yields from investments.

Interest expense increased 375% from \$262,000 for the thirteen-week period ended June 26, 2003 to \$1,245,000 for the thirteen-week period ended June 26, 2004, primarily due to interest expense of approximately \$788,000 related to the issuance of \$153 million convertible debt offering in the second quarter of 2004 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 June 28, 2003, we recorded a loss on the sale of fixed assets of \$2,000. For the thirteen week period ended June 26, 2004, we recorded a gain on the sale of fixed assets of \$85,000 primarily due to the sale of laboratory and computer equipment, which were no longer used in operations.

### *Twenty-six Week Periods Ended June 28, 2003 and June 26, 2004*

**The results of operations for the twenty-six week period ended June 26, 2004 include the operations of Genesoft from February 6, 2004 to June 26, 2004.**

### *Revenues*

Total revenues decreased 44% from \$4,449,000 for the twenty-six week period ended June 28, 2003 to \$2,471,000 for the twenty-six week period ended June 26, 2004.



Biopharmaceutical revenues decreased 19% from \$2,911,000 for the twenty-six week period ended June 28, 2003 to \$2,371,000 for the twenty-six week period ended June 26, 2004, which reflects lower contract research revenue as a result of the completion last year of our research obligations with Amgen.

Revenues from Genomics Services decreased 93% from \$1,538,000 for the twenty-six week period ended June 28, 2003 to \$100,000 for the twenty-six week period ended June 26, 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 our anticipated launch of the sale of our FACTIVE tablets in September of 2004.

#### *Costs and Expenses*

Total costs and expenses increased 46% from \$26,368,000 for the twenty-six week period ended June 28, 2003 to \$38,501,000 for the twenty-six week period ended June 26, 2004. Cost of services decreased 100% from \$1,903,000 for the twenty-six week period ended June 28, 2003 to \$0 for the twenty-six week period ended June 26, 2004 due to the sale of the Genomics Services business to Agencourt in March 2003.

Research and development expenses include internal research and development expenses, research funded pursuant to arrangements with our strategic alliance partners, as well as clinical development costs and expenses. Research and development

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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 3% from \$11,053,000 for the twenty-six week period ended June 28, 2003 to \$11,361,000 for the twenty-six week period ended June 26, 2004. This increase was primarily due to the increase in our effort in clinical development research programs totaling \$3,677,000, offset by the decrease in our effort in early stage product discovery and development research programs totaling \$3,369,000.

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 \$3,991,000 in the second quarter of 2003, of which approximately \$291,000 was related to a reduction in work force, such as severance costs and outplacement services and approximately \$3,700,000 of impairment charges related to the value of laboratory and computer equipment no longer used in operations.

During the second quarter of 2003, we also recorded a one-time charge to convertible debt retirement expense of \$5,528,000 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 \$562,000 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.

Stock-based compensation increased 978% from \$227,000 for the twenty-six week period ended June 28, 2003 to \$2,446,000 for the twenty-six week period ended June 26, 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.

Selling, general and administrative expenses increased 252% from \$3,666,000 for the twenty-six week period ended June 28, 2003 to \$12,891,000 for the twenty-six week period ended June 26, 2004. The increases in selling, general and administrative expenses is due to increased sales and marketing personnel and related costs of approximately \$6,279,000, increased general and administrative personnel, hiring and consulting costs of approximately \$2,276,000, and legal and patent costs of approximately \$670,000 to support the launch of FACTIVE in September 2004. Selling, general and administrative expenses are expected to increase in the foreseeable future as we continue to expand our commercialization efforts related to FACTIVE.

### *Other Income and Expense*

Interest income increased 82% from \$380,000 for the twenty-six week period ended June 28, 2003 to \$690,000 for the twenty-six week period ended June 24, 2004 reflecting higher cash balances due to the convertible debt proceeds received in the second quarter of 2004 as well as higher

interest rate yields from investments.

Interest expense increased 58% from \$972,000 for the twenty-six week period ended June 28, 2003 to \$1,540,000 for the twenty-six week period ended June 26, 2004, primarily due to interest expense of approximately \$788,000 related to the issuance of \$153 million convertible debt offering in the second quarter of 2004 along with approximately \$283,000 related to non-cash interest expense related to the facility lease liability which was recorded during the quarter ended March 27, 2004.

For the twenty-six week period ended June 28, 2003, we recorded a loss on the sale of fixed assets of \$132,000, primarily reflecting the transfer of fixed assets associated with the Genomics Services business to Agencourt. For the twenty-six week period ended June 26, 2004, we recorded a gain on the sale of fixed assets of \$126,000, 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, subscription fees, government grants, borrowings under equipment lending facilities and capital leases and proceeds from the sale of debt and equity securities.

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As of June 26, 2004, we had cash, cash equivalents and short-term and long-term marketable securities of approximately \$226,100,000, which includes \$18,800,000 of restricted cash.

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. 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 \$875,000 outstanding under this borrowing arrangement at June 26, 2004. Under this arrangement, we are required to maintain certain financial ratios, including minimum levels of unrestricted cash. We had no additional borrowing capacity under this financing agreement at June 26, 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 \$12,607,000 and \$21,515,000 for the twenty-six week periods ended June 28, 2003 and June 26, 2004, respectively. Cash used in operating activities for the twenty-six week period ended June 28, 2003 was due primarily to our net loss

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and decreases in accounts payable and accrued expenses and deferred revenue as well as increases in prepaid expenses and unbilled costs and fees. These uses of cash were partially offset by decreases in interest receivable, accounts receivable and non-cash expenses, such as depreciation and amortization and interest expense as well as increase clinical trial expense accrual. Cash used in our operating activities for the twenty-six week period ended June 26, 2004 was due primarily to our net loss and increases in interest receivable, unbilled costs and fees, prepaid expenses and other current assets as well as increases in deferred revenue and accrued facility impairment charge. These uses of cash were partially offset by increases in accounts payable, accrued expenses, accrued interest payable, clinical trial expense accrual and decreases in accounts receivable and non-cash expenses, such as depreciation and amortization expense, interest expense, and write-off of in-process technology.

Our investing activities provided cash of approximately \$23,100,000 for the twenty-six week period ended June 28, 2003 and used cash of approximately \$141,210,000 for the twenty-six week period ended and June 26, 2004. Cash provided by our investing activities for the twenty-six week period ended June 28, 2003 was primarily due to net proceeds of marketable securities of \$22,200,000 and net proceeds from sale of property and equipment of \$327,000. Cash used by our investing activities for the twenty-six week period ended June 26, 2004 was primarily related to \$14,989,000 of merger costs, net purchases of marketable securities of

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\$112,400,000, and net purchases of property and equipment of \$102,000. These uses of cash were partially offset by a decrease in other assets of \$1,322,000 and an increase in restricted cash of \$15,100,000.

Capital expenditures totaled \$106,000 and \$343,000 for the twenty-six week periods ended June 28, 2003 and June 26, 2004, respectively, primarily consisting of purchases of computer and related equipment.

Our financing activities used cash of approximately \$11,400,000 for the twenty-six week period ended June 28, 2003 primarily due to payments on retirement of convertible notes payable of \$10,000,000 and payments of long-term obligations of \$2,500,000, partially offset by proceeds received from settlement of a legal claim of \$613,000 and the proceeds from the issuance of stock under the employee stock purchase plan of \$260,000. Our financing activities provided cash of approximately \$229,022,000 for the twenty-six week period ended June 26, 2004, primarily due to net proceeds from the issuance of convertible notes of \$147,404,000, net proceeds from issuance of stock through private placement of \$80,864,000, proceeds from exercise of stock options and warrants of \$1,327,000 and proceeds from the issuance of stock under the employee stock purchase plan. These proceeds were partially offset by payments of long-term obligations of \$768,000.

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.

***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):

<u>2004</u>	<u>2005</u>	<u>2006</u>	<u>2007</u>	<u>2008</u>	<u>2009 &amp; Thereafter</u>
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Operating Leases	\$ 2,526	\$ 5,171	\$ 5,277	\$ 4,366	\$ 4,519	\$ 8,865
Sublease Income	(1,436)	(2,458)	(2,374)	(1,497)	(1,549)	(2,570)
	\$ 1,090	\$ 2,713	\$ 2,903	\$ 2,869	\$ 2,970	\$ 6,289
Capital lease obligations (a)	845	300				
Convertible promissory notes (b)	3,416	5,346	5,346	5,346	5,346	193,931
Total contractual obligations	\$ 5,315	\$ 8,359	\$ 8,249	\$ 8,215	\$ 8,316	\$ 200,220

(a) Includes interest payments.

(b) Upon the closing of the Genesoft merger, we exchanged approximately \$22 million of Company convertible promissory notes for a line 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

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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.

### **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 six 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 second 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.



**Table of Contents****PART II****Item 1. Legal Proceedings**

None

**Item 2. Changes in Securities**

On May 10, 2004, May 25, 2004 and June 4, 2004, the Company sold \$125 million, \$24.75 million and \$3 million, respectively, of its 3.5% senior convertible promissory notes due April 2011 in a private placement under Section 4(2) of the Securities Act of 1933, as amended (the Securities Act ) to qualified institutional buyers as defined by Rule 144A of the Securities Act. These notes are convertible into our common stock at the option of the holders at a conversion price of \$6.64 per share.

**Item 3. Defaults Upon Senior Securities**

None

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

Our annual meeting of shareholders was held on April 13, 2004. At the meeting, our shareholders took the following actions:

- (i) Election of directors.

	<b>For</b>	<b>Withheld</b>
David B. Singer	52,025,560	5,354,451
Robert J. Hennessey	51,972,620	5,406,391
Luke B. Evnin, Ph.D.	56,431,052	948,959
Vernon R. Loucks, Jr.	56,181,235	1,198,776
Steven M. Rauscher	51,994,584	5,385,427
William S. Reardon	56,343,090	1,036,921
William J. Rutter, Ph.D.	56,401,331	978,680
Norbert G. Reidel, Ph.D.	56,249,274	1,130,737
David K. Stone	56,336,240	1,043,771

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- (ii) To amend the Company's Articles of Organization to change its name to Oscient Pharmaceuticals Corporation.

<u>For</u>	<u>Against</u>	<u>Abstain</u>
56,231,749	864,697	283,565

- (iii) To approve an amendment to the Employee Stock Purchase Plan, as amended, authorizing an additional 750,000 shares of common stock, par value \$0.10 per share, to be reserved for issuance under the plan.

<u>For</u>	<u>Against</u>	<u>Abstain</u>
32,697,452	1,054,747	104,006

- (iv) To approve an amendment to the 2001 Incentive Plan, authorizing an additional 6,000,000 shares of common stock, par value \$0.10 per share, to be reserved for issuance under the plan.

<u>For</u>	<u>Against</u>	<u>Abstain</u>
25,097,824	8,636,152	122,229

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(v) To ratify the selection of Ernst & Young LLP as the Company's auditors for the year ending December 31, 2004.

<u>For</u>	<u>Against</u>	<u>Abstain</u>
56,998,310	246,721	134,980

**Item 5. Other Information**

None

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

<u>Exhibit No.</u>	<u>Description</u>
4.1	Indenture dated as of May 10, 2004, between the Registrant and U.S. Bank National Association, as trustee, including the form of 3.5% Convertible Subordinated Note due 2011 attached as an exhibit thereto. <sup>1</sup>
4.2	Pledge Agreement dated as of May 10, 2004 by and among the Registrant and U.S. Bank National Association as Trustee and Pledged Securities Intermediary. <sup>2</sup>
4.3	Registration Rights Agreement dated as of May 10, 2004 by and among the Registrant and J.P. Morgan Securities Inc. and Merrill Lynch, Pierce, Fenner & Smith Incorporated as Initial Purchasers. <sup>3</sup>
4.4	Indenture dated as of May 10, 2004, between the Registrant and U.S. Bank National Association, as trustee, including the form of 3.5% Convertible Subordinated Note due 2011 attached as an exhibit thereto. <sup>4</sup>
4.5	Pledge Agreement dated as of May 10, 2004 by and among the Registrant and U.S. Bank National Association as Trustee and Pledged Securities Intermediary. <sup>5</sup>
4.6	Registration Rights Agreement dated as of May 25, 2004 by and among the Registrant and Smithfield Fiduciary LLC. <sup>6</sup>
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.
99.1	Risk Factors

<sup>1</sup> Filed as an exhibit to the Registrant's Registration Statement on Form S-3 (No. 333-118026) and incorporated herein by reference.

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<sup>2</sup> Filed as an exhibit to the Registrant's Registration Statement on Form S-3 (No. 333-118026) and incorporated herein by reference.

<sup>3</sup> Filed as an exhibit to the Registrant's Registration Statement on Form S-3 (No. 333-118026) and incorporated herein by reference.

<sup>4</sup> Filed as an exhibit to the Registrant's Registration Statement on Form S-3 (No. 333-118026) and incorporated herein by reference.

<sup>5</sup> Filed as an exhibit to the Registrant's Registration Statement on Form S-3 (No. 333-118026) and incorporated herein by reference.

<sup>6</sup> Filed as an exhibit to the Registrant's Registration Statement on Form S-3 (No. 333-118026) and incorporated herein by reference.

### **b) Reports on Form 8-K**

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

- 1) Report on Form 8-K filed on April 13, 2004 to report that Genome Therapeutics Corp. issued a press release announcing that its shareholders approved a change in the company's name to Oscient Pharmaceuticals Corporation.
- 2) Report on Form 8-K/A filed on April 16, 2004 announcing GeneSoft Pharmaceuticals, Inc.'s financial results for the fiscal year ended December 31, 2003 and the Company's *pro forma* financial statements following the merger with GeneSoft Pharmaceuticals, Inc.
- 3) Report on Form 8-K filed on May 3, 2004 to report that the Company issued a press release announcing its intention to issue convertible notes pursuant to Rule 144A under the Securities Act of 1933.
- 4) Report on Form 8-K filed on May 4, 2004 to report that the Company issued a press release announcing the pricing of convertible notes to be issued pursuant to Rule 144A under the Securities Act of 1933.
- 5) Report on Form 8-K filed on May 10, 2004 to report that the Company issued a press release announcing the completion of an issuance of convertible notes pursuant to Rule 144A under the Securities Act of 1933.

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- 6) Report on Form 8-K filed on May 10, 2004 to report that the Company issued a press release announcing its financial results for its first fiscal quarter ended March 27, 2004.
  
- 7) Report on Form 8-K filed on May 25, 2004 to report that the Company issued a press release announcing the completion of an additional issuance of convertible notes pursuant to Rule 144A under the Securities Act of 1933.

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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

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Stephen Cohen

Senior Vice President & Chief Financial Officer

(Principal Financial Officer)

August 10, 2004

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**OSCIENT PHARMACEUTICALS CORPORATION AND SUBSIDIARIES**

**EXHIBIT INDEX**

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
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.
99.1	Risk Factors

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