

GENOME THERAPEUTICS CORP

Form 10-Q

November 12, 2003

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## SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

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### FORM 10-Q

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

For the Quarterly Period Ended: September 27, 2003

.. **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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## GENOME THERAPEUTICS CORP.

(Exact name of registrant as specified in its charter)

MASSACHUSETTS  
(State or other jurisdiction of

incorporation or organization)

04-2297484  
(I.R.S. Employer

Identification no.)

100 BEAVER STREET

WALTHAM, MASSACHUSETTS 02453

(Address of principal executive offices) (Zip code)

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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**

**31,432,245 Shares**  
**Outstanding November 07, 2003**

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**GENOME THERAPEUTICS CORP. AND SUBSIDIARY**

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**Table of Contents****GENOME THERAPEUTICS CORP. AND SUBSIDIARY****CONSOLIDATED BALANCE SHEETS (UNAUDITED)**

	December 31, 2002	September 27, 2003
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 14,228,507	\$ 14,270,060
Marketable securities (held-to-maturity)	32,584,384	9,832,126
Marketable securities (available-for-sale)	485,550	982,643
Interest receivable	784,372	239,604
Accounts receivable	2,043,862	179,253
Unbilled costs and fees	714,468	128,785
Prepaid expenses and other current assets	444,402	351,011
	<u>51,285,545</u>	<u>25,983,482</u>
Total Current Assets		
Property and Equipment, at cost:		
Laboratory and scientific equipment	21,906,312	18,443,609
Leasehold improvements	8,923,916	7,516,159
Equipment and furniture	1,281,932	1,232,431
	<u>32,112,160</u>	<u>27,192,199</u>
Less Accumulated depreciation	21,973,715	23,285,588
	<u>10,138,445</u>	<u>3,906,611</u>
Long-term Marketable Securities (held-to-maturity)	3,567,757	701,417
Other Assets	853,387	148,300
	<u>\$ 65,845,134</u>	<u>\$ 30,739,810</u>
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
Current Liabilities:		
Current maturities of long-term obligations	\$ 2,623,986	\$ 1,166,667
Accounts payable	2,175,047	246,921
Accrued expenses	4,079,148	3,335,998
Clinical trial expense accrual	4,329,792	5,208,018
Deferred revenue	1,566,145	852,348
	<u>14,774,118</u>	<u>10,809,952</u>
Total Current Liabilities		
Long-term Obligations, net of current maturities	15,654,292	583,333
Shareholders' Equity:		
Common stock and additional paid-in capital	161,283,225	173,414,437
Accumulated deficit	(125,775,400)	(154,230,822)
Other shareholders' equity	(91,101)	162,910
	<u>35,416,724</u>	<u>19,346,525</u>
Total Shareholders' Equity		
	<u>\$ 65,845,134</u>	<u>\$ 30,739,810</u>



**Table of Contents****GENOME THERAPEUTICS CORP. AND SUBSIDIARY****CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)**

	<u>Thirteen Week Period Ended</u>		<u>Thirty-Nine Week Period Ended</u>	
	<u>September 28, 2002</u>	<u>September 27, 2003</u>	<u>September 28, 2002</u>	<u>September 27, 2003</u>
<b>Revenues:</b>				
Biopharmaceutical	\$ 1,844,312	\$ 2,607,967	\$ 6,205,997	\$ 5,519,381
Genomics Services	3,155,353	261,573	10,942,853	1,799,240
<b>Total revenues</b>	<b>4,999,665</b>	<b>2,869,540</b>	<b>17,148,850</b>	<b>7,318,621</b>
<b>Costs and Expenses:</b>				
Cost of services	3,071,806		10,184,284	1,902,561
Research and development	9,206,536	6,487,736	25,339,525	17,541,087
Restructuring charge		742,166		4,732,914
Convertible Debt Retirement Expense		12,500		5,540,333
Selling, general and administrative	2,629,129	1,569,768	6,874,944	5,462,929
<b>Total costs and expenses</b>	<b>14,907,471</b>	<b>8,812,170</b>	<b>42,398,753</b>	<b>35,179,824</b>
<b>Loss from operations</b>	<b>(9,907,806)</b>	<b>(5,942,630)</b>	<b>(25,249,903)</b>	<b>(27,861,203)</b>
<b>Other Income (Expense):</b>				
Interest income	400,636	80,619	1,426,240	460,280
Interest expense	(557,865)	(23,653)	(1,402,081)	(995,977)
Gain (loss) on sale of fixed assets	(7,582)	73,636	50,865	(58,522)
<b>Net Other Income (Expense)</b>	<b>(164,811)</b>	<b>130,602</b>	<b>75,024</b>	<b>(594,219)</b>
<b>Net loss</b>	<b>\$ (10,072,617)</b>	<b>\$ (5,812,028)</b>	<b>\$ (25,174,879)</b>	<b>\$ (28,455,422)</b>
<b>Net Loss per Common Share:</b>				
Basic and diluted	\$ (0.44)	\$ (0.22)	\$ (1.10)	\$ (1.16)
<b>Weighted Average Common Shares Outstanding:</b>				
Basic and diluted	23,032,463	25,956,357	22,880,971	24,581,226

See Notes to Consolidated Condensed Financial Statements.

**Table of Contents****GENOME THERAPEUTICS CORP. AND SUBSIDIARY****CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)**

	<b>Thirty-nine Week Period Ended</b>	
	<b>September 28, 2002</b>	<b>September 27, 2003</b>
<b>Cash Flows from Operating Activities:</b>		
Net loss	\$ (25,174,879)	\$ (28,455,422)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	3,673,273	2,109,412
Non-cash restructuring charge		3,700,075
Non-cash convertible debt retirement expense		4,012,269
Non-cash interest expense	357,425	1,225,454
(Gain) loss on disposal of equipment and leasehold improvements	(50,866)	58,522
Amortization of deferred compensation	362,622	621,205
Changes in assets and liabilities		
Interest receivable	425,177	544,768
Accounts receivable	(159,726)	1,864,609
Unbilled costs and fees	(429,787)	585,683
Prepaid expenses and other current assets	832,697	93,391
Accounts payable	(715,867)	(1,928,126)
Accrued expenses	483,356	(162,054)
Clinical trial expense accrual	2,703,538	878,226
Deferred revenue	(2,672,252)	(713,797)
Net cash used in operating activities	(20,365,289)	(15,565,785)
<b>Cash Flows from Investing Activities:</b>		
Purchases of marketable securities	(32,186,896)	(5,281,108)
Proceeds from maturities of marketable securities	34,809,258	30,674,413
Purchases of property and equipment	(2,741,451)	(106,445)
Proceeds from sale of property and equipment	67,600	470,269
Decrease in restricted cash	200,000	
(Increase) decrease in other assets	(773,097)	705,087
Net cash (used in) provided by investing activities	(624,586)	26,462,216
<b>Cash Flows from Financing Activities:</b>		
Proceeds from exercise of stock options	12,547	360,643
Proceeds from issuance of stock under the employee stock purchase plan	452,932	453,499
Proceeds from issuance of common stock		500,000
Gross proceeds from convertible notes payable	15,000,000	
Proceeds from borrowings on equipment financing arrangement	3,500,000	
Proceeds from a section 16 claim with an investor		584,711
Payments made upon retirement of convertible notes payable		(10,000,000)
Payments on long-term obligations	(3,745,373)	(2,753,731)
Net cash provided by (used in) financing activities	15,220,106	(10,854,878)
<b>Net (Decrease) Increase in Cash and Cash Equivalents</b>	<b>(5,769,769)</b>	<b>41,553</b>
<b>Cash and Cash Equivalents, beginning of period</b>	<b>24,805,385</b>	<b>14,228,507</b>

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<b>Cash and Cash Equivalents, end of period</b>	<u>\$ 19,035,616</u>	<u>\$ 14,270,060</u>
<b>Supplemental Disclosure of Cash Flow Information:</b>		
Interest paid during period	<u>\$ 839,008</u>	<u>\$ 568,500</u>
Income tax paid during period	<u>\$ 37,503</u>	<u>\$ 24,999</u>
<b>Supplemental Disclosure of Non-cash Investing and Financing Activities:</b>		
Unrealized gain (loss) on marketable securities	<u>\$ (367,699)</u>	<u>\$ 271,801</u>
Issuance of warrant in connection with convertible notes payable	<u>\$ 1,735,059</u>	<u>\$ 149,781</u>
Issuance of common stock related to interest payable under convertible notes	<u>\$ 288,494</u>	<u>\$ 581,096</u>
Issuance of common stock upon conversion of convertible notes payable	<u>\$</u>	<u>\$ 5,000,000</u>

See Notes to Consolidated Condensed Financial Statements.



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**GENOME THERAPEUTICS CORP. AND SUBSIDIARY**

**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, 2002 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 31, 2003 and amended on September 29, 2003.

**(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

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 subsidiary, Collaborative Securities Corp. (a Massachusetts Securities Corporation). All intercompany accounts and transactions have been eliminated in consolidation.

*(b) Revenue Recognition*

Biopharmaceutical revenues consist of government research grants and license fees, contract research and milestone payments from alliances with pharmaceutical companies. GenomeVision™ 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.

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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. 101, *Revenue Recognition*. Milestone payments will be recognized upon achievement of the milestone as long as the milestone is nonrefundable, 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.

**Table of Contents***(c) 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, warrants and unvested restricted stock that are not included in diluted net loss per share totaled 4,699,968 and 4,852,945 shares of the Company's common stock during the thirteen and thirty-nine week periods ended September 28, 2002 and September 27, 2003, respectively.

*(d) 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:

	<b>Number of Significant Customers</b>	<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>	<b>F</b>
Thirteen-week period ended:							
September 28, 2002	2	46%	26%				
September 27, 2003	3			12%	10%	62%	
Thirty-nine week period ended:							
September 28, 2002	2	45%	26%				
September 27, 2003	4	17%		14%	11%	47%	

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:

<b>Percentage of Total Accounts Receivable</b>						
<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>	<b>F</b>	<b>G</b>
—	—	—	—	—	—	—

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As of:			
December 31, 2002	23%	37%	27%
September 27, 2003	47%	42%	

### *(e) Reclassification*

Certain amounts have been reclassified in the prior period financial statements to conform to the current period presentation.

**Table of Contents***(f) 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.

*(g) 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 nonowner sources. For the thirteen and thirty-nine week periods ended September 28, 2002, comprehensive loss includes a loss of approximately \$236,000 and \$366,000, respectively, related to the decrease in fair market value of common shares which were received in connection with the exercise of a warrant under its collaboration agreement with Versicor Inc., which subsequently merged with Biosearch Italia S.p.A and changed its name to Vicuron Pharmaceuticals Inc. (Vicuron). For the thirteen and thirty-nine week periods ended September 27, 2003, comprehensive loss includes a gain of approximately \$118,000 and \$272,000, respectively, related to the increase in fair market value of these common shares. These common shares are classified as available-for-sale short-term marketable securities in the accompanying balance sheet. In October 2003, these common shares were sold through the Nasdaq National Market and the Company recorded a realized gain of approximately \$608,000 related to this transaction. See Note 5 for further discussion.

*(h) 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>
<b>Thirty-nine week period ended September 28, 2002</b>			
Revenues	\$ 10,942,853	\$ 6,205,997	\$ 17,148,850
Cost of services	10,184,284		10,184,284
Externally funded research and development costs		3,888,205	3,888,205
Gross profit	758,569	2,317,792	3,076,361
Company-funded research & development costs		21,451,320	21,451,320

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Total research and development costs		25,339,525	25,339,525
Thirty-nine week period ended September 27, 2003			
Revenues	\$ 1,799,240	\$ 5,519,381	\$ 7,318,621
Cost of services	1,902,561		1,902,561
Externally funded research and development costs		3,670,317	3,670,317
Gross profit (loss)	(103,321)	1,849,064	1,745,743
Company-funded research & development costs		13,870,770	13,870,770
Total research and development costs		17,541,087	17,541,087

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The measure of gross profit for the Genomics Services segment is the total segment revenues less cost of services. 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. Total research and development costs are equal to externally funded research and development costs and Company funded research and development costs. The Company does not allocate assets by operating segment.

*(i) 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 tables illustrate 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 Transition and Disclosure", for all employee stock options granted using the Black-Scholes option pricing model prescribed by SFAS No. 123.

	Thirteen Week Period Ended		Thirty-nine Week Period Ended	
	September 28, 2002	September 27, 2003	September 28, 2002	September 27, 2003
Net loss as reported	\$ (10,072,617)	\$ (5,812,028)	\$ (25,174,879)	\$ (28,455,422)
Add: Stock-based employee compensation cost, included in the determination of net loss as reported	68,217	91,009	362,622	621,205
Less: Total stock-based compensation expense determined under the fair value method for all employee awards	(993,294)	(653,314)	(3,987,920)	(1,769,142)
<b>Pro forma net loss</b>	<b>\$ (10,997,694)</b>	<b>\$ (6,374,333)</b>	<b>\$ (28,800,177)</b>	<b>\$ (29,603,359)</b>
<b>Basis and diluted net loss per share</b>				
As reported	\$ (0.44)	\$ (0.22)	\$ (1.10)	\$ (1.16)
<b>Pro forma</b>	<b>\$ (0.48)</b>	<b>\$ (0.25)</b>	<b>\$ (1.26)</b>	<b>\$ (1.20)</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 effects on 2002 and 2003 pro forma 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.

*(j) Recent Accounting Pronouncements*

In January 2003, the FASB issued Interpretation No. 46, *Consolidation of Variable Interest Entities* (FIN No. 46) to clarify the conditions under which assets, liabilities and activities of another entity should be consolidated into the financial statements of a company. FIN No. 46 requires the consolidation of a variable interest entity by a company that bears the majority of the risk of loss from the variable interest entity's activities, is entitled to receive a majority of the variable interest entity's residual returns or both. The consolidation requirements of FIN No. 46 apply immediately to variable interest entities created after January 31, 2003 and to entities created before February 1, 2003 in the fiscal or interim period beginning after December 15, 2003. The Company is currently evaluating the impact, if any, of FIN No. 46 on its consolidated results of operations and financial position.



**Table of Contents****(3) RESTRUCTURING PLAN**

As part of our effort to reduce costs and expenses, we adopted a plan in the second quarter of 2003 to substantially reduce our research effort in internally funded early-stage target discovery programs. Under this plan, 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, outplacement services and a noncash charge for the acceleration of vesting of previously granted stock options and approximately \$3,700,000 of impairment charges related to the value of laboratory and computer equipment no longer used in operations.

In the third quarter of 2003, 6 employees who had previously been notified were terminated. We recorded an additional \$742,000 of severance costs related to the reduction in work force. During the fourth quarter of 2003, we will record additional severance related costs of approximately \$480,000 as we move closer to completion of this process.

A detail of our accrual for severance costs and outplacement services during the second and third quarters of 2003 is as follows:

	<u>Q2</u>	<u>Q3</u>
Accrued severance costs, beginning of the quarter	\$	\$
Payments	(253,021)	(147,415)
Amounts Accrued	253,021	733,696
	<u>          </u>	<u>          </u>
Accrued severance costs, end of the quarter	\$	\$ 586,281

Payments represent payments of severance and outplacements services costs. Amounts accrued represents additional severance and outplacements services costs accrued related to the Company's restructuring plan.

**(4) SALE OF GENOMICS SERVICES**

Genomics Services revenue consists of government sequencing grants, fees and royalties received from custom gene sequencing and analysis and subscription fees from PathoGenome™ Database.

On March 14, 2003, the Company completed the sale of its Genomics Services business to Agencourt Bioscience Corporation (Agencourt). As part of the Asset Purchase Agreement (the Agreement), the Company transferred its gene sequencing operations, including both commercial and government customer contracts and certain personnel and equipment, to Agencourt in exchange for an upfront cash payment of \$200,000 and shares of Agencourt common stock. The Company will also receive royalties on gene sequencing revenue earned by Agencourt that is related to the transferred business for a period of two years after the date of sale. The Company retains rights to its PathoGenome™ Database, including all associated intellectual property, subscriptions and royalty rights on products developed by subscribers.

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As discussed above, the Company will receive royalties on gene sequencing revenue earned by Agencourt that is related to the transferred business for a period of two years after the date of sale. Accordingly, the cash flows from the Genomics Services group will not have been completely eliminated from the ongoing operations of the Company as a result of the disposal transaction. As a result, the sale does not initially qualify as a discontinued operation as defined by SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. As of September 27, 2003, the Company has recognized approximately \$394,000 in royalties from Agencourt.

In connection with the sale of its Genomics Services business, the Company determined that certain equipment related to this segment will no longer be used and will be abandoned subsequent to the sale. As a result, the Company revised the estimated useful lives of this equipment and recorded additional depreciation expense of \$669,000 during the fourth quarter of 2002. The Company also evaluated and wrote down its excess inventory of disposables related to the Genomics Services business by \$312,000 during the fourth quarter of 2002. Additionally, through this divestiture, the Company eliminated approximately 60 full-time positions, of which approximately 49 employees were not offered employment with Agencourt. The Company recorded a charge of approximately \$703,000 in the first quarter of 2003, of which approximately \$130,000 was related to the transfer of assets to Agencourt and approximately \$573,000 associated with the reduction in work force, such as severance costs and

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outplacement services. As of September 27, 2003, all payments related to both severance and outplacement services have been made.

**(5) CASH EQUIVALENTS AND INVESTMENTS**

The Company follows the provisions of SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. At December 31, 2002 and September 27, 2003, the Company's investments include 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. The average maturity of the Company's investments was approximately 3.2 months at September 27, 2003. At September 27, 2003, the Company had a net unrealized gain of \$1,523, which is the difference between the amortized cost and the fair value of the held-to-maturity investments.

At September 27, 2003, the Company's short-term marketable securities also included shares of common stock of Vicuron received in connection with its collaboration agreement with Vicuron dated March 10, 1997 and shares of common stock of Agencourt received in connection with the Agreement dated March 14, 2003. The Company is accounting for these shares in accordance with SFAS No. 115 as available-for-sale securities and as a result, the shares are recorded at fair value. On October 10, 2003 and October 13, 2003, subsequent to quarter-end, the Company sold all of its Vicuron common shares through the Nasdaq National Market and received gross proceeds of approximately \$811,000. The Company recorded a realized gain of \$608,000 related to this transaction.

At December 31, 2002 and September 27, 2003, 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><u>December 31, 2002</u></b>				
Cash and Cash Equivalents:				
Cash	\$ 11,128,507	\$	\$	\$ 11,128,507
Debt securities	3,100,000			3,100,000
<b>Total cash and cash equivalents</b>	<b>\$ 14,228,507</b>	<b>\$</b>	<b>\$</b>	<b>\$ 14,228,507</b>
Investments Held-to-Maturity:				
Short-term marketable securities	\$ 32,584,384	\$ 89,220	\$ (3,067)	\$ 32,670,537
Long-term marketable securities	3,567,757	14,311	(1,862)	3,580,206
<b>Total investments</b>	<b>\$ 36,152,141</b>	<b>\$ 103,531</b>	<b>\$ (4,929)</b>	<b>\$ 36,250,743</b>
<b><u>December 31, 2002 Available-for-Sale</u></b>				
Investment in equity securities	\$ 200,160	\$ 285,390	\$	\$ 485,550
<b><u>September 27, 2003</u></b>				

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Cash and Cash Equivalents:

Cash	\$ 8,370,168	\$	\$	\$ 8,370,168
Debt securities	5,899,892	(115)		5,899,777
	<u>                    </u>	<u>                    </u>	<u>                    </u>	<u>                    </u>
Total cash and cash equivalents	\$ 14,270,060	\$ (115)	\$	\$ 14,269,945
	<u>                    </u>	<u>                    </u>	<u>                    </u>	<u>                    </u>

Investments Held-to-Maturity:

Short-term marketable securities	\$ 9,832,126	\$ 5,283	\$ (2,343)	\$ 9,835,066
Long-term marketable securities	701,417		(1,417)	700,000
	<u>                    </u>	<u>                    </u>	<u>                    </u>	<u>                    </u>
Total investments	\$ 10,533,543	\$ 5,283	\$ (3,760)	\$ 10,535,066
	<u>                    </u>	<u>                    </u>	<u>                    </u>	<u>                    </u>

September 27, 2003 Available-for-Sale

Investment in equity securities	\$ 425,453	\$ 557,190	\$	\$ 982,643
	<u>                    </u>	<u>                    </u>	<u>                    </u>	<u>                    </u>

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On March 5, 2002, the Company sold convertible notes payable to two institutional investors in a private placement transaction, raising \$15 million in gross proceeds. The convertible notes payable were convertible into shares of the Company's common stock at the option of the holder, at a price of \$8.00 per share, subject to certain adjustments. The maturity date of the convertible notes payable was December 31, 2004. Interest on the convertible notes payable accrued at 6% annually and the interest was payable, in cash or in stock, semi-annually on June 30 and December 31 of each year. The investors also received a warrant to purchase up to an aggregate of 487,500 shares of common stock at an exercise price of \$8.00 per share, subject to certain adjustments. The warrant was exercisable at the time the convertible notes payable were converted or if certain other redemptions or repayments of the convertible notes payable occurred and terminated upon the earlier of four years from the date of such conversion or December 31, 2008. The warrant was valued, using the Black-Scholes option pricing model, at approximately \$1,736,000. The amount was recorded as a discount to long-term obligations and amortized to interest expense over the term of the convertible notes payable. Additionally, the Company is obligated to issue a warrant to purchase up to 100,000 shares of common stock at an exercise price of \$15.00 per share to its placement agent in this transaction. The warrant is exercisable over a three-year term which commenced upon the closing of the notes payable transaction. This warrant was valued, using the Black-Scholes option pricing model, at \$244,000. As of September 27, 2003, this warrant had not been issued.

On June 4, 2003, the Company entered into an Amendment, Redemption and Exchange Agreement with the 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 common stock of the Company and the (c) issuance to the investors of new warrants in exchange for warrants previously issued to the investors.

Under the terms of the agreement, the Company 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 the Company's common stock. The Company 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 511,250 shares of the Company's common stock at an exercise price of \$3.53 per share. The new warrants include provisions for adjustment of the exercise price and the number of shares issuable upon exercise in the event of stock splits, stock dividends, reverse stock splits, and issuances by the Company of shares of its capital stock at prices below the exercise price or the fair market value of the common stock if higher than such exercise price. The Company had also granted the investors a right of participation to purchase up to 33.33% of the amount of securities sold to investors in non-registered or "shelf" capital raising transactions (subject to certain exceptions), provided that if any such transaction exceeds \$15,000,000, then for the portion of the transaction that exceeds \$15,000,000, the investors have the right to purchase up to 20% of such excess amount sold to investors. In addition, each investor has the right to purchase at least \$1,000,000 of securities in any such transaction. The rights described in this paragraph are effective until the second anniversary of the closing date of the transaction.

The Company applies the provisions of SFAS No. 84, *Induced Conversions of Convertible Debt* and Emerging Issues Task Force Issue No. 02-15, *Determining Whether Certain Conversion of Convertible Debt to Equity Securities Are Within the Scope of FASB Statement No. 84*. SFAS 84 specifies the method of accounting for conversions of the convertible debt to equity securities when the debtor induces conversion of the debt by offering additional securities or other consideration to convertible debt holder. In 2003, the Company recorded a one-time charge to convertible debt retirement expense of \$5,540,000, which consisted of \$3,862,000 for the fair value of the incremental shares issued under the new agreement, \$150,000 for the incremental fair value of the

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exchange warrants using the Black-Scholes option pricing model, as well as \$574,000 of unamortized closing costs related to the original agreement and \$954,000 of unamortized cost related to the value of the original warrants.

In February 2002, the Company entered into a loan agreement for \$3,500,000, of which \$500,000 was used to refinance a portion of an existing line of credit. This loan is payable in twelve consecutive quarterly payments at the prevailing LIBOR rate (1.30% at September 27, 2003) plus 1.50%. The Company is required to maintain certain financial covenants pertaining to minimum cash balances. As of September 27, 2003, \$1.7 million was outstanding under the loan agreement, and the Company was in compliance with all of the covenants.

## **(7) PRODUCT DEVELOPMENT**

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, currently in a Phase III clinical trial for the prevention of bloodstream infections caused by vancomycin-resistant enterococci (VRE), as well as a Phase II clinical trial to assess the safety and efficacy of Ramoplanin to treat Clostridium difficile-associated diarrhea (CDAD). 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. The combined total of bulk product purchases and royalties is expected to be approximately 26% of the Company's net product sales.

For the clinical development of Ramoplanin, the Company recorded an expense of approximately \$4,539,000 and \$4,587,000 during the thirteen-week periods ended September 28, 2002 and September 27, 2003, respectively. For the thirty-nine week periods ended September 28, 2002 and September 27, 2003, the Company recorded an expense of approximately \$10,777,000 and \$8,660,000, respectively. The thirty-nine week period ended September 27, 2003 includes a favorable change in estimate of approximately \$3 million in the accrual for clinical development expenditures.

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

Research and development expenses primarily consist of salaries and related expenses for personnel 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. 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 1(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.

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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 thirty-nine week periods ended September 28, 2002 and September 27, 2003, the Company incurred approximately \$3,888,000 and \$3,670,000, respectively, related to its alliances.

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The Company has entered into the alliances described below with biopharmaceutical partners in order to discover, research, develop and commercialize products. Potential revenues (exclusive of royalty payments earned upon the successful commercialization of products) to be earned by the Company generally include an upfront license fee, sponsored /contract research payments and research and development and regulatory approval milestone payments. In the alliances summarized below, a portion of the total potential alliance revenues has already been earned with described future payments potentially yet to be realized. 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 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.

### (a) ASTRAZENECA

In August 1995, the Company entered into a strategic alliance with AstraZeneca (Astra), formerly Astra Hassle AB, to develop drugs, vaccines and diagnostic products effective against peptic ulcers or any other disease caused by *H. pylori*. The Company granted Astra exclusive access to the Company's *H. pylori* genomic sequence database and exclusive worldwide rights to make, use and sell products based on the Company's *H. pylori* technology. The agreement provided for a four-year research alliance (which ended in August 1999) to further develop and annotate the Company's *H. pylori* genomic sequence database, identify therapeutic and vaccine targets, and develop appropriate biological assays.

Under this agreement, Astra agreed to pay the Company, subject to the achievement of certain product development milestones, up to \$23.3 million (and possibly a greater amount if more than one product is developed under the agreement) in license fees, expense allowances, research funding and milestone payments. The Company has received a total of \$13.7 million in license fees, expense allowances, milestone payments, maintenance fees and research funding under the Astra agreement through September 27, 2003.

The Company will also be entitled to receive royalties on Astra's sale of products protected by the claims of patents licensed to Astra by the Company pursuant to the agreement or the discovery of which was enabled in a significant manner by the genomic data licensed to Astra by the Company. In its development of new anti-ulcer products, Astra has selected a novel lead series for advancement into lead optimization. As of March 31, 2003, Astra's exclusive access rights to the Company's *H. pylori* genomic sequence technology had terminated. The Company may enter into alliances in the future with other partners to develop drugs, vaccines and diagnostic products effective against peptic ulcers or any other disease caused by *H. pylori*.

The Company recognized no revenue under this agreement during the thirty-nine week periods ended September 28, 2002 and September 27, 2003.

### (b) SCHERING-PLOUGH

In December 1995, the Company entered into a strategic alliance and license agreement (the December 1995 agreement) with Schering Corporation and Schering-Plough Ltd. (collectively, Schering-Plough) providing for the use by Schering-Plough of the genomic sequence of *Staph. aureus* to identify and validate new gene targets for development of drugs to target *Staph. aureus* and other pathogens that have become resistant to current antibiotics. As part of this agreement, the Company granted Schering-Plough exclusive access to the Company's proprietary



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Staph. aureus genomic sequence database. The Company agreed to undertake certain research efforts to identify bacteria-specific genes essential to microbial survival and to develop biological assays to be used by Schering-Plough in screening natural product and compound libraries to identify antibiotics with new mechanisms of action.

Under this agreement, Schering-Plough paid an initial license fee and funded a research program through March 31, 2002. Schering-Plough paid the Company \$21.5 million in an up-front license fee, research funding and

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milestone payments through September 27, 2003. Subject to the achievement of additional product development milestones, Schering-Plough agreed to pay the Company up to an additional \$24.0 million in milestone payments.

The agreement grants Schering-Plough exclusive worldwide rights to make, use and sell pharmaceutical and vaccine products based on the genomic sequence databases licensed to Schering-Plough and on the technology developed in the course of the research program. The Company will be entitled to receive royalties on Schering-Plough's sale of therapeutic products and vaccines developed using the technology licensed. The Company had completed its research obligations under this alliance and had turned over validated drug targets and assays to Schering-Plough for high-throughput screening.

Under the December 1995 agreement, the Company recognized approximately \$0 and \$127,000 in revenues during the thirteen-week and thirty-nine week periods ended September 28, 2002, respectively, which consisted of alliance research revenue. The Company recognized no revenue in 2003.

In December 1996, the Company entered into its second strategic alliance and license agreement (the December 1996 agreement) with Schering-Plough. This agreement calls for the use of genomics to discover new pharmaceutical products for treating asthma. As part of the agreement, the Company employed its high-throughput disease gene identification, bioinformatics, and genomics sequencing capabilities to identify genes and associated proteins that can be utilized by Schering-Plough to develop pharmaceuticals and vaccines for treating asthma. Under this agreement, the Company has granted Schering-Plough exclusive access to (i) certain gene sequence databases made available under this research program, (ii) information made available to the Company under certain third-party research agreements, and (iii) an exclusive worldwide right and license to make, use and sell pharmaceutical and vaccine products based on the rights to develop and commercialize diagnostic products that may result from this alliance.

Under the December 1996 agreement (and subsequent extensions), Schering-Plough paid an initial license fee and an expense allowance to the Company and funded the research program through December 2002. In addition, upon completion of certain scientific developments, Schering-Plough has made or will potentially make milestone payments, as well as pay royalties based upon sales of therapeutic products developed from this collaboration. If all milestones are met, total payments to the Company will approximate \$81.0 million, excluding royalties. Of the total potential payments, approximately \$36.5 million represents license fees and research payments, and \$44.5 million represents milestone payments based on achievement of research and product development milestones. In December 2002, the Company had completed its research obligations under this alliance and the research program has advanced into high-throughput screening at Schering-Plough. A total of \$42.5 million has been received through September 27, 2003.

Under this agreement, the Company recognized approximately \$1,112,000 and \$0 in revenue during the thirteen-week periods ended September 28, 2002 and September 27, 2003, respectively, which consisted of alliance research revenue. For the thirty-nine week periods ended September 28, 2002 and September 27, 2003, the Company recognized approximately \$4,202,000 and \$115,000 in revenue, respectively, which consisted of alliance research revenue.

In September 1997, the Company entered into a third strategic alliance and license agreement (the September 1997 agreement) with Schering-Plough to use genomics to discover and develop new pharmaceutical products to treat fungal infections. Under this agreement, the Company employed its bioinformatics, high-throughput sequencing and functional genomics capabilities to identify and validate genes and associated proteins as drug discovery targets that can be utilized by Schering-Plough to develop novel antifungal treatments. Schering-Plough has received exclusive access to the genomic information developed in the alliance related to two fungal pathogens, *Candida albicans* and *Aspergillus fumigatus*. Schering-Plough has also received exclusive worldwide rights to make, use and sell products based on the technology developed during the course of the research program. In return, Schering-Plough agreed to fund a research program through March 31, 2002. If all milestones are met, total payments to the Company will approximate \$33.2 million, excluding royalties. Of the total potential payments,

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approximately \$10.2 million represents contract research payments and \$23.0 million represents milestone payments based on achievement of research and product development milestones. The Company has completed its research

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obligations under this alliance and has turned over validated drug targets and assays to Schering-Plough for high-throughput screening. A total of \$12.2 million has been received through September 27, 2003.

Under the September 1997 agreement, the Company recognized approximately \$6,000 and \$0 in revenue during the thirty-nine week periods ended September 28, 2002 and September 27, 2003, respectively.

Under certain circumstances, the Company may have an obligation to give Schering-Plough a right of first negotiation to develop with the Company certain of its asthma and infectious disease related discoveries if it decides to seek a third party collaborator to develop such discoveries.

(c) BIOMERIEUX

In September 1999, the Company entered into a strategic alliance with bioMerieux to develop, manufacture and sell in vitro diagnostic products for human clinical and industrial applications. As part of the alliance, bioMerieux purchased a subscription to the Company's PathoGenome Database, paid an up-front license fee, agreed to fund a research program for at least four years and pay royalties on future products. In addition, bioMerieux purchased \$3.75 million of the Company's common stock. The total amount of research and development funding, excluding subscription fees, approximates \$5.2 million for the four-year term of this agreement. The research and development funding will be recognized as the research services are performed over the four-year term of the agreement. Approximately \$5.2 million has been received through September 27, 2003.

The Company recognized approximately \$297,000 in revenue during both thirteen-week periods ended September 28, 2002 and September 27, 2003, which consisted of alliance research revenue and amortization of the up-front license fees. For both thirty-nine week periods ended September 28, 2002 and September 27, 2003, the Company recognized approximately \$891,000 in revenue, which consisted of alliance research revenue and amortization of the up-front license fees.

(d) WYETH

In December 1999, the Company entered into a strategic alliance with Wyeth to develop novel therapeutics for the prevention and treatment of osteoporosis. The alliance will focus on developing therapeutics, utilizing targets based on the characterization of a gene associated with a unique high bone mass trait.

The agreement provides for the Company to employ its established capabilities in positional cloning, bioinformatics and functional genomics in conjunction with Wyeth's drug discovery capabilities and its expertise in bone biology and the osteoporotic disease process to develop new pharmaceuticals. Under the terms of the agreement, Wyeth agreed to pay an up-front license fee, milestone payments and fund a research program for a minimum of two years with an option to extend. On December 30, 2002, Wyeth exercised its option to extend the research program to December 2003. If the research program continues for its full term and substantially all of the milestone payments are met, total payments to the Company, excluding royalties, would exceed \$119 million. Approximately \$10.0 million has been received through September 27, 2003.

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The Company recognized approximately \$261,000 and \$273,000 in revenue during the thirteen-week periods ended September 28, 2002 and September 27, 2003, respectively, which consisted of alliance research revenue. The Company recognized approximately \$784,000 and \$819,000 in revenue during the thirty-nine week periods ended September 28, 2002 and September 27, 2003, respectively, which consisted of alliance research revenue.

### (e) AMGEN

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. Both companies will participate in collaborative research efforts to discover one or more drug candidates suitable for development. The companies will, as part of the research activities, use genetic information, developed by the Company based on research conducted at the Creighton University Osteoporosis Research Center, which has been exclusively licensed to Amgen.

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Under the terms of the agreement, Amgen will pay the Company an up-front license fee, and fund a multi-year research program, which includes milestone payments and royalties on sales of therapeutics products developed from this alliance. Contingent upon the success of the discovery, development and commercialization activities, Amgen may also purchase common shares of the Company. Amgen's equity ownership in the Company will be limited to no more than 4.99% of the Company's outstanding shares. If all milestones are met, total payments to the Company will approximate \$67 million, excluding royalties if a single product is developed and a maximum of \$104 million, excluding royalties, if more than one product is developed under the agreement. Of the total potential payments, approximately \$59.0 million represents research payments, milestone payments and a license fee, and \$8.0 million represents an equity investment in the Company by Amgen. Approximately \$4.5 million has been received through September 27, 2003 consisting of \$4.0 million in research payments, a milestone payment and a license fee and \$.5 million in an equity investment in the Company by Amgen.

The Company will receive royalties on product sales ranging from 4%-10% depending on the level of those sales. We may elect to participate in the funding of the clinical development program, in which case we may co-promote the product in the U.S. and Canada and receive either increased royalties on sales or participate in profits from product sales in the U.S. and Canada.

The Company recognized approximately \$1,783,000 in revenue during the thirteen week period ended September 27, 2003, and \$3,415,000 during the thirty-nine week period ended September 27, 2003. These revenues consisted of alliance research revenue, a milestone payment and amortization of the up-front license fee.

## **(9) SUBSEQUENT FINANCING**

On September 29, 2003 and October 15, 2003, the Company completed a private placement of 5,220,000 shares of common stock at \$2.50 per share resulting in proceeds of approximately \$12 million, net of issuance costs. In connection with this private placement, the Company issued warrants to purchase 2,610,000 shares of common stock at an exercise price of \$3.48 per share, subject to certain adjustments. These warrants remain exercisable for a period of five years and cannot be exercised during the six-month period immediately following the transaction.

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

Certain information contained in this report should be considered forward-looking statements as defined by the Private Securities Litigation Reform Act of 1995. These statements represent, among other things, the expectations, beliefs, plans and objectives of management and/or assumptions underlying or judgments concerning the future financial performance and other matters discussed in this document. The words may, will, should, plan, believe, estimate, intend, anticipate, project, and expect and similar expressions are intended to identify 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 our lead product candidate, Ramoplanin, such as (i) our inability to obtain regulatory approval to commercialize Ramoplanin due to negative, inconclusive or insufficient clinical data and (ii) delays in the progress of our clinical trials for Ramoplanin, and increased cost, due to the pace of enrollment of patients in the trials or fluctuations in the infection rate of enrolled patients;

our inability or the inability of our alliance partners to successfully develop and obtain regulatory approval of products based on our genomics information;

our history of operating losses and our need to raise future capital to support our 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; 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 that we may make with the Securities and Exchange Commission from time to time.

## **Overview**

We are a biopharmaceutical company focused on the discovery and development of pharmaceutical products for specialty markets. Our lead product candidate, Ramoplanin, is in development for the prevention, treatment and control of serious hospital-based infections. Ramoplanin is currently in a Phase III clinical trial for the prevention of bloodstream infections caused by vancomycin-resistant enterococci (VRE), and in a Phase II clinical trial for the treatment of Clostridium difficile-associated diarrhea (CDAD). Our biopharmaceutical portfolio also includes seven major product discovery and development alliances with pharmaceutical companies including Amgen, AstraZeneca, bioMérieux, Schering-Plough and Wyeth. During 2002, we also maintained a Genomics Services business, providing drug discovery services to pharmaceutical and biotechnology companies and to the National Human Genome Research Institute. As part of our continued evolution into a

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biopharmaceutical company, this business unit was divested in March 2003.

Our biopharmaceutical product candidates are all currently in development or discovery phases and are neither approved by the U.S. Food and Drug Administration nor available for commercial sale.



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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 the product development in the United States of Ramoplanin, currently in a Phase III clinical trial for the prevention of bloodstream infections caused by vancomycin-resistant enterococci (VRE), as well as a Phase II clinical trial to assess the safety and efficacy of Ramoplanin to treat Clostridium difficile-associated diarrhea (CDAD). For more detail on this project, see Major Research and Development Projects Ramoplanin below.

Our primary sources of revenue are from alliance agreements with pharmaceutical company partners. Currently, we have seven major product discovery alliances, and we currently receive contract research funding from three of these alliances. For more detail on this project, see Major Research and Development Projects Biopharmaceutical Alliances below.

In the first quarter of 2003 and past fiscal years, we have 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 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. Furthermore, we retain the capabilities necessary to satisfy the research needs of our existing product-focused alliances, as well as potential new alliances. We do not expect the sale of the Genomics Services business to have a significant impact on our net loss during the next two years, as a result of reductions in costs associated with this sale and our rights to receive royalties on gene sequencing revenue earned by Agencourt that is related to the transferred business for a period of two years from the date of sale.

In connection with the sale of our Genomics Services business, we determined that certain equipment related to this segment will no longer be used and will be abandoned subsequent to the sale. As a result, we revised the estimated useful lives of this equipment and recorded additional depreciation expense of \$669,000 during the fourth quarter of 2002. We also evaluated and wrote down our excess inventory of disposables related to the Genomics Services business by \$312,000 during the fourth quarter of 2002. Additionally, through this divestiture, we eliminated approximately 60 full-time positions, of which approximately 49 employees were not offered employment with Agencourt. We recorded a charge of approximately \$703,000 in the first quarter of 2003, of which approximately \$130,000 was related to the transfer of assets to Agencourt and approximately \$573,000 associated with the reduction in work force, such as severance costs and outplacement services. As of September 27, 2003, all payments related to both severance and out placement services have been made.

We receive payments under our biopharmaceutical business primarily from our product discovery alliances based on license fees, contract research and milestone payments during the term of the alliance. 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 have incurred significant operating losses since our inception. As of September 27, 2003, we had an accumulated deficit of approximately \$154.2 million. Our losses are primarily from costs associated with prior operating businesses and research and development expenses. These costs have exceeded our revenues generated by our alliances, subscription agreements and government grants. Our results of operations have fluctuated from period to period and may continue to fluctuate in the future based upon the timing, amount and type of funding. We expect to incur additional operating losses in the future.



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### Major Research and Development Projects

#### Ramoplanin

Our ongoing clinical trials and other development activities for Ramoplanin constitute our most significant research and development project comprising 23% of total research and development expenditures for fiscal 2001 (development activity and associated expense did not commence until the fourth quarter of 2001 upon our acquisition of an exclusive license for the product), 43% of total research and development expenditures for fiscal 2002, 49% of total research and development expenditures for the thirteen-week period ended September 28, 2002, 71% of total research and development for the thirteen-week period ended September 27, 2003, 43% of total research and development expenditures for the thirty-nine week period ended September 28, 2002 and 49% of total research and development expenditures for the thirty-nine week period ended September 27, 2003. Expenses for Ramoplanin comprise 46% 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 the product development in the United States of Ramoplanin, currently in a Phase III clinical trial for the prevention of bloodstream infections caused by vancomycin-resistant enterococci (VRE), as well as a Phase II clinical trial to assess the safety and efficacy of Ramoplanin to treat Clostridium difficile-associated diarrhea (CDAD). 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 bulk product purchases and royalties is expected to be approximately 26% of our net product sales.

As of September 27, 2003, the status of the Ramoplanin clinical program was as follows:

In a Phase III clinical trial for the prevention of bloodstream infections caused by vancomycin-resistant enterococci (VRE).

In a Phase II clinical trial to assess safety and efficacy of Ramoplanin to treat Clostridium difficile-associated diarrhea (CDAD).

In 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 initial goal of the Ramoplanin program is to obtain marketing approval from the FDA for the VRE and CDAD indications. We are also likely to explore programs for other indications to be determined. 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**

A second major research and development project of ours is the support we provide to fulfill our research obligations with our pharmaceutical company partners under our strategic alliances.

The research and development expense to support these alliances was 30% of total research and development expenses in fiscal 2001, 16% of total research and development expenses in fiscal 2002, 12% of total research and development expenses for the thirteen-week period ended September 28, 2002, 20% of total research and development expenses for the thirteen-week period ended September 27, 2003, 15% of total research and development expenses for the thirty-nine week period ended September 28, 2002 and 21% of total research and development expenses for the thirty-nine week period ended September 27, 2003. Research and development expense to support our alliances was 35% of the total research and development expense from January 1, 1995 through September 27, 2003. Our first alliance was formed in 1995.

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

AstraZeneca, August 1995:

Goal: Develop pharmaceutical, vaccine and diagnostic products effective against gastrointestinal infections or any other disease caused by *Helicobacter pylori* (H. pylori).

Status: The contract research phase of the alliance concluded August 1999 and the program transitioned into AstraZeneca's pipeline. The alliance is currently in the lead optimization phase.

Schering-Plough, December 1995:

Goal: Identify new gene targets for the development of novel antibiotics utilizing our *Staphylococcus aureus* (Staph. Aureus) genomic database.

Status: 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.

Schering-Plough, December 1996:

Goal: Develop new pharmaceuticals for the treatment of asthma through the identification of genes and associated proteins.

Status: In December 2002, we completed our research obligations and Schering-Plough has advanced the program into high-throughput screening.

Schering-Plough, September 1997:

Goal: Development of new pharmaceutical products to treat fungal infections.

Status: In March 2002, we completed our research obligations, turning over validated drug targets and assays and Schering-Plough has advanced the program into high-throughput screening.

BioMerieux, September 1999:

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Goal: Develop, manufacture and sell in vitro pathogen diagnostics products for human clinical and industrial applications.

Status: Contract research phase is ongoing.

Wyeth, December 1999:

Goal: Develop drugs based on our genetic research to treat osteoporosis.

Status: Contract research phase is ongoing and high-throughput screening has commenced.

Amgen, December 2002:

Goal: Identify and develop novel therapeutic agents for bone diseases, including osteoporosis based on our genetic research.

Status: Contract research phase is in 1 year and we are currently focusing on gene discovery. In August 2003, we received a payment from Amgen upon attaining a research milestone under this alliance.

Our ability to obtain the goal for each of these alliances is subject to numerous risks, including our inability to realize the potential of our initial discoveries due to scientific failures or lack of skilled personnel. In addition, we are heavily dependant upon our alliance partners to carry out 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

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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. A failure to obtain additional milestone payments and to advance our alliances towards product approvals would have a significant negative impact on our operations, financial position and liquidity.

### **Internally Funded Research Program**

The Company conducts its own internally funded program, falling into two primary categories:

The discovery and research of potential drug candidates, primarily in the anti-infective area. Depending on the potential indication, we make a decision to develop the compound, partner it, or outlicense it to a third party. To date, our internal efforts have produced two novel lead series, which have reached the optimization stage.

The acquisition of assets, primarily population resources, combined with our disease gene identification platform with the goal of making discoveries that will facilitate new biopharmaceutical alliances.

As a combined category, these research efforts represented 47% of total research and development expenditures in fiscal 2001, 41% of expenditures in fiscal 2002, 39% of expenditures during the thirteen-week period ended September 28, 2002, 9% of expenditures during the thirteen-week period ended September 27, 2003, 42% of expenditures during the thirty-nine week period ended September 28, 2002 and 30% of expenditures during the thirty-nine week period ended September 27, 2003. These efforts comprised 48% of the total research and development expense during January 1, 1995 through September 27, 2003.

Our ability to obtain our goals for our internally funded research program is subject to numerous risks, including our inability to make new discoveries due to scientific failures or lack of skilled personnel and our inability to successfully license resources, such as population genetics data sets, for which there is intense competition. Even if we succeed in identifying novel lead series or making genetic discoveries related to a disease, we may not be successful in developing these discoveries further due to lack of internal resources and the inability to find a strategic partner in an increasingly competitive environment for strategic alliances. Due to all of these uncertainties, we can provide no assurance that we will ever receive any material cash inflows from this program.

### **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 this and other accounting policies, see Note 1 in the Notes to the Consolidated Condensed Financial Statements of this Report. 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, contract research and milestone payments from alliances with pharmaceutical companies. GenomeVision 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



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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. 101, Revenue Recognition. Milestone payments will be recognized upon achievement of the milestone as long as the milestone is 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.

### *Clinical Trial Expense Accrual*

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. During the second quarter of 2003, we adjusted our accrual for clinical trial expenditures to reflect our most current estimate of liabilities outstanding to outside parties, resulting in a \$3 million reduction in research and development expenditures in the second quarter of 2003. We believe that the estimates that we made as of September 27, 2003 are reflective of the actual expenses incurred as of that date. 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 September 28, 2002 and September 27, 2003*

#### *Revenues*

Total revenues decreased 43% from \$5,000,000 for the thirteen-week period ended September 28, 2002 to \$2,870,000 for the thirteen-week period ended September 27, 2003.

Biopharmaceutical revenues increased 41% from \$1,844,000 for the thirteen-week period ended September 28, 2002 to \$2,608,000 for the thirteen-week period ended September 27, 2003, primarily due to a milestone payment received this quarter under our Amgen alliance aimed at utilizing genetic information to discover and commercialize new therapeutics for bone diseases, including osteoporosis.

Revenues from Genomics Services decreased 92% from \$3,155,000 for the thirteen-week period ended September 28, 2002 to \$262,000 for the thirteen-week period ended September 27, 2003 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

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Services business to Agencourt. We expect that our revenues will continue to be lower in comparison to last year as a result of the sale of the Genomics Services business.

### *Costs and Expenses*

Total costs and expenses decreased 41% from \$14,907,000 for the thirteen-week period ended September 28, 2002 to \$8,812,000 for the thirteen-week period ended September 27, 2003. Cost of services decreased from \$3,072,000 for the thirteen-week period ended September 28, 2002 to \$0 for the thirteen-week period ended September 27, 2003 due to the sale of the Genomics Services business to Agencourt.

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 and the cost of materials used in sequencing activities and research and development. Other research and development expenses

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include fees paid to consultants and outside service providers, information technology and facilities costs. Research and development expenses decreased 30% from \$9,207,000 for the thirteen-week period ended September 28, 2002 to \$6,488,000 for the thirteen-week period ended September 27, 2003. This decrease was primarily due to the reduction in expenses relating to our internally funded early-stage target discovery research programs of approximately \$2,993,000.

As part of our continued effort to restructure our internally funded research programs, we recorded a restructuring charge of approximately \$742,000 for the thirteen week period ended September 27, 2003, consisting primarily of severance costs and outplacement services.

Selling, general and administrative expenses decreased 40% from \$2,629,000 for the thirteen-week period ended September 28, 2002 to \$1,570,000 for the thirteen-week period ended September 27, 2003 primarily reflecting a reduction in support staff, and consulting fees.

### *Other Income and Expense*

Interest income decreased 80% from \$401,000 for the thirteen-week period ended September 28, 2002 to \$81,000 for the thirteen-week period ended September 27, 2003 reflecting lower interest rate yields from investments, as well as a decrease in funds available for investment.

Interest expense decreased 96% from \$558,000 for the thirteen-week period ended September 28, 2002 to \$24,000 for the thirteen-week period ended September 27, 2003 reflecting lower interest expense incurred during the current quarter due to the retirement in the last quarter of the convertible notes payable, as well as the pay-off of an equipment financing arrangement in the first quarter of 2003.

For the thirteen week period ended September 28, 2002, we recorded a loss on the sale of fixed assets of \$8,000. For the thirteen week period ended September 27, 2003, we recorded a gain on the sale of fixed assets of \$74,000, primarily reflecting the sale of laboratory and computer equipment, which were no longer used in operations.

### *Thirty-nine Week Periods Ended September 28, 2002 and September 27, 2003*

#### *Revenues*

Total revenues decreased 57% from \$17,149,000 for the thirty-nine week period ended September 28, 2002 to \$7,319,000 for the thirty-nine week period ended September 27, 2003.

Biopharmaceutical revenues decreased 11% from \$6,206,000 for the thirty-nine week period ended September 28, 2002 to \$5,519,000 for the thirty-nine week period ended September 27, 2003, which reflects lower contract research revenue as a result of the completion last year of our research obligations with Schering-Plough, partially offset by sponsored research revenue and a milestone payment earned from our new alliance with Amgen, which we entered into in December 2002.

Revenues from Genomics Services decreased 84% from \$10,943,000 for the thirty-nine week period ended September 28, 2002 to \$1,799,000 for the thirty-nine week period ended September 27, 2003 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. We expect that our revenues will continue to be lower in comparison to last year as a result of the sale of the Genomics Services business.

*Costs and Expenses*

Total costs and expenses decreased 17% from \$42,399,000 for the thirty-nine week period ended September 28, 2002 to \$35,180,000 for the thirty-nine week period ended September 27, 2003. Cost of services decreased 81% from \$10,184,000 for the thirty-nine week period ended September 28, 2002 to \$1,903,000 for the thirty-nine week period ended September 27, 2003 due to the sale of the Genomics Services business to Agencourt in March 2003.

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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 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 decreased 31% from \$25,340,000 for the thirty-nine week period ended September 28, 2002 to \$17,541,000 for the thirty-nine week period ended September 27, 2003. This decrease was primarily due to the reduction in our effort in internally funded early-stage target discovery research programs totaling \$5,464,000, decrease in cost and expenses associated with the decrease in biopharmaceutical revenue of approximately \$218,000, as well as a reduction in expenses incurred in the clinical development of Ramoplanin of approximately \$2,116,000. The reduction in clinical development expenses reflects primarily a reduction in our accrual for clinical trial expenditures to outside parties of \$3,043,000, partially offset by higher support expenditures such as personnel, consulting and material costs of \$927,000.

As part of our effort to reduce costs and expenses, we have substantially reduced our research effort in internally funded early-stage target discovery programs. As a result, we recorded a restructuring charge of approximately \$4,733,000, of which approximately \$987,000 was related to a reduction in work force, such as severance costs and outplacement services and approximately \$3,746,000 of impairment charges related to the value of laboratory and computer equipment no longer used in operations.

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

Selling, general and administrative expenses decreased 21% from \$6,875,000 for the thirty-nine week period ended September 28, 2002 to \$5,463,000 for the thirty-nine week period ended September 27, 2003 primarily reflecting reduction in support staff and personnel related expenditures, consulting fees and hiring expenses.

### *Other Income and Expense*

Interest income decreased 68% from \$1,426,000 for the thirty-nine week period ended September 28, 2002 to \$460,000 for the thirty-nine week period ended September 27, 2003 reflecting lower interest rate yields from investments, as well as a decrease in funds available for investment.

Interest expense decreased 29% from \$1,402,000 for the thirty-nine week period ended September 28, 2002 to \$996,000 for the thirty-nine week period ended September 27, 2003 reflecting lower interest expense incurred this year due to the early retirement of the convertible notes payable, as well as the pay-off of an equipment financing arrangement in the first quarter of 2003.

For the thirty-nine week period ended September 28, 2002, we recorded a gain on the sale of fixed assets of \$51,000. For the thirty-nine week period ended September 27, 2003, we recorded a loss on the sale of fixed assets of \$59,000, primarily reflecting the transfer of fixed assets associated with the Genomics Services business to Agencourt.

**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.

As of September 27, 2003, we had cash, cash equivalents and short-term and long-term marketable securities of approximately \$25,786,000.

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On March 5, 2002, we sold convertible notes payable to two institutional investors in a private placement transaction, raising \$15 million in gross proceeds. The investors also received a warrant to purchase up to an aggregate of 487,500 shares of common stock at an exercise price of \$8.00 per share, subject to certain adjustments. Additionally, we are obligated to issue a warrant to purchase up to 100,000 shares of common stock at an exercise price of \$15.00 per share to our placement agent in this transaction. The warrant is exercisable over a three-year term which commenced upon the closing of the notes payable transaction. This warrant was valued, using the Black-Scholes option pricing model, at \$244,000.

On June 4, 2003, we entered into an Amendment, Redemption and Exchange Agreement with the 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 511,250 shares of our common stock at an exercise price of \$3.53 per share. The new warrants include provisions for adjustment of the exercise price and the number of shares issuable upon exercise in the event of stock splits, stock dividends, reverse stock splits, and issuances by us of shares of our capital stock at prices below the exercise price or the fair market value of the common stock if higher than such exercise price. We had also granted the investors a right of participation to purchase up to 33.33% of the amount of securities sold to investors in non-registered or shelf capital raising transactions (subject to certain exceptions), provided that if any such transaction exceeds \$15,000,000, then for the portion of the transaction that exceeds \$15,000,000, the investors have the right to purchase up to 20% of such excess amount sold to investors. In addition, each investor shall have the right to purchase at least \$1,000,000 of securities in any such transaction. The rights described in this paragraph are effective until the second anniversary of the closing date of the transaction.

On September 10, 2003, we sold 146,333 shares of common stock to Amgen, a strategic alliance partner, resulting in gross proceeds of approximately \$500,000.

On September 29, 2003 and October 15, 2003, subsequent to quarter-end, the Company completed a private placement of 5,220,000 shares of common stock at \$2.50 per share resulting in proceeds of approximately \$12 million, net of issuance costs. In connection with this private placement, the Company issued warrants to purchase 2,610,000 shares of common stock at an exercise price of \$3.48 per share, subject to certain adjustments. These warrants remain exercisable for a period of five years and cannot be exercised during the six-month period immediately following the transaction.

We have a loan agreement under which we have financed certain office and laboratory equipment and leasehold improvements. We had approximately \$1,750,000 outstanding under this borrowing arrangement at September 27, 2003. This amount is repayable over the next 16 months, with \$1,167,000 repayable over the next 12 months. 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 September 27, 2003.

Our operating activities used cash of approximately \$20,365,000 and \$15,566,000 for the thirty-nine week periods ended September 28, 2002 and September 27, 2003, respectively. Cash used in operating activities for the thirty-nine week period ended September 28, 2002 was due primarily to our net loss and decreases in accounts payable and deferred revenue and increases in accounts receivable and unbilled costs and

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fees. These uses of cash were partially offset by decreases in interest receivable, prepaid expenses and other current assets and increases in accrued expenses and clinical trial expense accrual, as well as non-cash expenses, such as depreciation and amortization and interest expense. Cash used in our operating activities for the thirty-nine week period ended September 27, 2003 was due primarily to our net loss and decreases in accounts payable and deferred revenue. These uses of cash were partially offset by decreases in interest receivable, accounts



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receivable, unbilled costs and fees, prepaid expenses and other current assets, as well as non-cash expenses, such as depreciation and amortization, restructuring charges, convertible debt retirement expenses and interest expense.

Our investing activities used cash of approximately \$625,000 for the thirty-nine week period ended September 28, 2002 and provided cash of approximately \$26,462,000 for the thirty-nine week period ended and September 27, 2003. Cash used by our investing activities for the thirty-nine week period ended September 28, 2002 was primarily due to purchases of marketable securities and property and equipment, as well as an increase in other assets which was related to the recording of deferred financing costs associated with the convertible notes payable described above. These uses of cash were partially offset by the conversion of marketable securities to cash and cash equivalents. Cash provided by our investing activities for the thirty-nine week period ended September 27, 2003 was primarily through the conversion of marketable securities to cash and cash equivalents, proceeds received from the sale of property and equipment, as well as a reduction in other assets related to the expensing of the deferred financing costs associated with the convertible notes payable, partially offset by purchases of marketable securities and equipment.

Capital expenditures totaled \$2,741,000 and \$106,000 for the thirty-nine week periods ended September 28, 2002 and September 27, 2003, respectively, primarily consisting of purchases of laboratory and computer equipment. We currently estimate that we will acquire no more than \$200,000 in capital equipment in 2003 consisting of office and computer equipment, and additions to leasehold improvements.

Our financing activities provided cash of approximately \$15,220,000 for the thirty-nine week period ended September 28, 2002 primarily from proceeds received from the sale of convertible notes payable totaling \$15 million in gross proceeds, proceeds received from entering into an additional loan agreement for \$3,500,000, of which \$500,000 was used to refinance a portion of an existing line of credit, as well as proceeds received from issuances of stock under the employee stock purchase plan. These proceeds from financing activities were partially offset by payments of long-term obligations of \$3,745,000. Our financing activities used cash of approximately \$10,855,000 for the thirty-nine week period ended September 27, 2003, primarily due to the retirement of the \$15 million convertible notes payable through a \$10 million cash payment and conversion of \$5 million into our shares of common stock. We issued 1,945,586 shares of our common stock related to this transaction. Our financing activities also used cash of approximately \$2,754,000 for payments of other long-term obligations. These uses of cash were partially offset by proceeds received of \$500,000 from the sale of equity, proceeds received of approximately \$585,000, net of legal costs, from a settlement of a Section 16 claim with an investor, as well as proceeds received from the exercise of stock options and purchases under the employee stock purchase plan totaling approximately \$814,000.

At December 31, 2002, we had net operating loss and tax credit (investment and research) carryforwards of approximately \$120,307,000 and \$9,084,000, respectively, available to reduce federal taxable income and federal income taxes, respectively, 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 the limitations of the carryforward period.

We plan to continue to invest in our internal research and development programs, primarily in our lead candidate, Ramoplanin, currently in a Phase III clinical trial for the prevention of bloodstream infections caused by vancomycin-resistant enterococci (VRE), and a Phase II clinical trial to assess the safety and efficacy of Ramoplanin to treat *Clostridium difficile*-associated diarrhea (CDAD). We expect to incur approximately \$12-14 million in clinical development expenditures during 2003.

We believe that our existing capital resources are adequate for approximately eighteen months under our current rate of investment in research and development. There is no assurance, however, that changes in our plans or events affecting our operations will not result in accelerated or unexpected expenditures.

We plan to continue to explore opportunities to reduce our costs, including the formation of additional alliances and partnerships aimed at reducing unsponsored research.

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We plan to seek additional funding in the next twelve months through public or private financing in order to fund our clinical development and research projects. Additional financing may not be available when needed or if available, it may not be on terms acceptable to us. Any additional capital that we raise by issuing equity or convertible debt securities will dilute the ownership of existing stockholders.

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

Our market risks, and the ways we manage them, are summarized in management's discussion and analysis of financial condition and results of operations as of December 31, 2002, included in the Company's Form 10-K for the year ended December 31, 2002 and in Exhibit 99.1 to this Report on Form 10-Q. The Company's Annual Report on Form 10-K was filed with the Securities and Exchange Commission on March 31, 2003 and amended on September 29, 2003. There have been no material changes in the first nine months of 2003 to such risks or our management of such risks.

**ITEM 4: CONTROLS AND PROCEDURES**

The Company's principal executive officer and its principal financial officer undertook an evaluation of the Company's disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this report and concluded that the Company's controls and procedures were effective.

There were no changes in the Company's internal control over financial reporting during the period covered by this report that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

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**PART II**

**Item 1.     *Legal Proceedings***

None

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

On September 10, 2003, we sold, pursuant to the private placement exemption under Section 4(2) of the Securities Act of 1933, as amended, 146,333 shares of our common stock at approximately \$3.42 per share to Amgen, Inc., a strategic alliance partner, resulting in gross proceeds of approximately \$500,000.

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

None

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

None

**Item 5.     *Other Information***

None

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

**(a) Exhibits:**

<u>Exhibit No.</u>	<u>Description</u>
10.1	Separation agreement with Richard Labaudiniere, dated July 9, 2003.
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.

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- 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

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

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

Report on Form 8-K filed August 13, 2003 to report that the Company issued a press release announcing its financial results for its second fiscal quarter ended June 28, 2003.

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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.

GENOME THERAPEUTICS CORP.

/s/ Stephen Cohen

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Stephen Cohen,

Senior Vice President & Chief Financial Officer

(Principal Financial Officer)

November 11, 2003



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**GENOME THERAPEUTICS CORP. AND SUBSIDIARY**

**EXHIBIT INDEX**

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99.1	Risk Factors

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