

GENOME THERAPEUTICS CORP

Form 10-Q

May 13, 2003

Table of Contents

---

# SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

---

## FORM 10-Q

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

For the Quarterly Period Ended: March 29, 2003

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

Commission File No: 0-10824

# 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)

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

## Edgar Filing: GENOME THERAPEUTICS CORP - Form 10-Q

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act.

Yes " No x

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

**COMMON STOCK**

**23,659,325 Shares**

**\$0.10 PAR VALUE**

**Outstanding May 9, 2003**

---

---

**Table of Contents**

**GENOME THERAPEUTICS CORP. AND SUBSIDIARY**

**INDEX TO FINANCIAL INFORMATION AND OTHER INFORMATION**

	<b><u>Page</u></b>
Part I	
Financial Information (unaudited):	
<u>Consolidated Condensed Balance Sheets as of December 31, 2002 and March 29, 2003</u>	3
<u>Consolidated Statements of Operations for the thirteen-week periods ended March 30, 2002 and March 29, 2003</u>	4
<u>Consolidated Statements of Cash Flows for the thirteen-week periods ended March 30, 2002 and March 29, 2003</u>	5
<u>Notes to Consolidated Condensed Financial Statements</u>	6-13
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	14-19
<u>Quantitative and Qualitative Disclosures about Market Risk</u>	20
<u>Controls and Procedures</u>	20
Part II	
Other Information:	
<u>Other Information</u>	21-22
<u>Signature</u>	23
<u>Certifications</u>	24-25
<u>Exhibit Index</u>	26

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

	<b>December 31, 2002</b>	<b>March 29, 2003</b>
<b>ASSETS</b>		
<b>Current Assets:</b>		
Cash and cash equivalents	\$ 14,228,507	\$ 16,662,243
Marketable securities (held-to-maturity)	32,584,384	23,109,280
Marketable securities (available-for-sale)	485,550	705,848
Interest receivable	784,372	418,036
Accounts receivable	2,043,862	140,892
Unbilled costs and fees	714,468	866,067
Prepaid expenses and other current assets	444,402	654,995
<b>Total current assets</b>	<b>51,285,545</b>	<b>42,557,361</b>
Property and Equipment, at cost:		
Laboratory and scientific equipment	21,906,312	21,105,194
Leasehold improvements	8,923,916	7,516,159
Equipment and furniture	1,281,932	1,232,431
	32,112,160	29,853,784
Less Accumulated depreciation	21,973,715	20,864,653
	10,138,445	8,989,131
Long-term Marketable Securities (held-to-maturity)	3,567,757	2,944,058
Other Assets	853,387	765,250
	<b>\$ 65,845,134</b>	<b>\$ 55,255,800</b>
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
<b>Current Liabilities:</b>		
Current maturities of long-term obligations	\$ 2,623,986	\$ 1,166,667
Accounts payable	2,175,047	509,500
Accrued expenses	4,079,148	2,589,571
Clinical trial expense accrual	4,329,792	6,736,648
Deferred revenue	1,566,145	1,397,727
<b>Total current liabilities</b>	<b>14,774,118</b>	<b>12,400,113</b>
Long-term Obligations, net of current maturities	15,654,292	15,094,394
Shareholders Equity	35,416,724	27,761,293
	<b>\$ 65,845,134</b>	<b>\$ 55,255,800</b>

See Notes to Consolidated Condensed Financial Statements



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

	<b>Thirteen-Week Period Ended</b>	
	<b>March 30, 2002</b>	<b>March 29, 2003</b>
<b>Revenues:</b>		
Biopharmaceutical	\$ 2,433,725	\$ 1,454,357
Genomics Services	3,730,792	1,284,693
<b>Total revenues</b>	<b>6,164,517</b>	<b>2,739,050</b>
<b>Costs and Expenses:</b>		
Cost of services	3,413,790	1,902,561
Research and development	7,846,081	6,715,440
Selling, general and administrative	2,057,385	2,224,364
<b>Total costs and expenses</b>	<b>13,317,256</b>	<b>10,842,365</b>
<b>Loss from operations</b>	<b>(7,152,739)</b>	<b>(8,103,315)</b>
<b>Other Income (Expense):</b>		
Interest income	530,932	232,079
Interest expense	(216,090)	(710,452)
Gain (loss) on sale of fixed assets	53,121	(130,001)
<b>Net Other Income (Expense)</b>	<b>367,963</b>	<b>(608,374)</b>
<b>Net loss</b>	<b>\$ (6,784,776)</b>	<b>\$ (8,711,689)</b>
<b>Net Loss per Common Share:</b>		
Basic and diluted	\$ (0.30)	\$ (0.37)
<b>Weighted Average Common Shares Outstanding:</b>		
Basic and diluted	22,798,224	23,595,026

See Notes to Consolidated Condensed Financial Statements.

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

	<b>Thirteen-Week Period Ended</b>	
	<b>March 30, 2002</b>	<b>March 29, 2003</b>
<b>Cash Flows from Operating Activities:</b>		
Net loss	\$ (6,784,776)	\$ (8,711,689)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	1,196,538	867,855
Non-cash interest expense		153,181
(Gain) loss on disposal of fixed assets	(53,121)	130,001
Amortization of deferred compensation	213,032	347,170
Changes in assets and liabilities		
Interest receivable	595,984	366,336
Accounts receivable	301,023	1,902,970
Unbilled costs and fees	(971,241)	(151,599)
Prepaid expenses and other current assets	295,153	(210,593)
Accounts payable	(887,125)	(1,665,547)
Accrued expenses	(835,255)	(1,035,878)
Clinical trial expense accrual	3,130,751	2,406,856
Deferred revenue	(2,105,241)	(168,418)
Net cash used in operating activities	<u>(5,904,278)</u>	<u>(5,769,355)</u>
<b>Cash Flows from Investing Activities:</b>		
Purchases of marketable securities	(1,043,768)	(4,059,489)
Proceeds from sale of marketable securities	10,187,749	13,933,000
Purchases of property and equipment	(1,316,024)	(106,445)
Proceeds from sale of property and equipment	67,408	257,902
Decrease in restricted cash	200,000	
(Increase) decrease in other assets	(931,927)	88,137
Net cash provided by investing activities	<u>7,163,438</u>	<u>10,113,105</u>
<b>Cash Flows from Financing Activities:</b>		
Proceeds from exercise of stock options	6,881	730
Proceeds from issuance of stock under the employee stock purchase plan	259,151	259,654
Gross proceeds from convertible notes payable	15,000,000	
Proceeds from loan agreement	3,500,000	
Payments on long-term obligations	(2,065,692)	(2,170,398)
Net cash provided by (used in) financing activities	<u>16,700,340</u>	<u>(1,910,014)</u>
<b>Net Increase in Cash and Cash Equivalents</b>	<b>17,959,500</b>	<b>2,433,736</b>
<b>Cash and Cash Equivalents, beginning of period</b>	<b>24,805,385</b>	<b>14,228,507</b>
<b>Cash and Cash Equivalents, end of period</b>	<b><u>\$ 42,764,885</u></b>	<b><u>\$ 16,662,243</u></b>

**Supplemental Disclosure of Cash Flow Information:**

Interest paid during period	\$ 230,913	\$ 469,134
	<u>                    </u>	<u>                    </u>
Income tax paid during period	\$ 12,501	\$ 9,999
	<u>                    </u>	<u>                    </u>

**Supplemental Disclosure of Non-cash Investing and Financing Activities:**

Unrealized gain (loss) on marketable securities	\$ 613,733	\$ (4,994)
	<u>                    </u>	<u>                    </u>
Issuance of common stock related to interest payable under convertible notes	\$	\$ 453,699
	<u>                    </u>	<u>                    </u>

See Notes to Consolidated Condensed Financial Statements.



**Table of Contents**

**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.

**(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 license fees, contract research and milestone payments from alliances with pharmaceutical companies. Genomics Services revenues consist of government grants, fees received from custom gene sequencing and analysis services and subscription fees from the PathoGenome™ Database. Revenues from contract research, government grants, the PathoGenome™ Database subscription fees, and custom gene sequencing and analysis services are recognized over the respective contract periods as the services are performed, provided

## Edgar Filing: GENOME THERAPEUTICS CORP - Form 10-Q

there is persuasive evidence of an arrangement, the fee is fixed or determinable and collection of the related receivable is probable. License fees are 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.

### *(c) Net Loss Per Share*

Basic and diluted earnings per share were 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 4,610,055 and 5,300,647 shares of the Company's common stock during the thirteen-week periods ended March 30, 2002 and March 29, 2003, respectively.

**Table of Contents***(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>Thirteen-week period ended:</b>					
March 30, 2002	2	48%	30%		
March 29, 2003	3	36%		13%	38%

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

	<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>As of:</b>						
December 31, 2002	23%				37%	27%
March 29, 2003			10%		77%	

*(e) 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.

## Edgar Filing: GENOME THERAPEUTICS CORP - Form 10-Q

### *(f) 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. During the thirteen-week period ended March 29, 2003, the Company recorded approximately \$5,000 to comprehensive loss 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). These common shares are classified as available-for-sale short-term marketable securities in the accompanying balance sheet. See Note 4 for further discussion.

### *(g) 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

**Table of Contents**

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 3).

	<u>Genomics Services</u>	<u>Biopharmaceutical</u>	<u>Total</u>
<b>Thirteen week period ended March 30, 2002</b>			
Revenues	\$ 3,730,792	\$ 2,433,725	\$ 6,164,517
Gross profit	317,002	932,636	1,249,638
Company-funded research & development		6,344,992	6,344,992
<b>Thirteen week period ended March 29, 2003</b>			
Revenues	\$ 1,284,693	\$ 1,454,357	\$ 2,739,050
Gross profit	(617,868)	588,255	(29,613)
Company-funded research & development		5,849,338	5,849,338

The Company does not allocate assets by operating segment.

**(3) SALE OF GENOMICS SERVICES**

Genomics Services revenue consists of government sequencing grants, fees 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 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 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.

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.

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

## Edgar Filing: GENOME THERAPEUTICS CORP - Form 10-Q

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 \$700,000 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. Refer to Note 2(g) for certain segment information related to Genomics Services.

**Table of Contents****(4) 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 March 29, 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 6.8 months at March 29, 2003. At March 29, 2003, the Company had a net unrealized gain of approximately \$68,000, which is the difference between the amortized cost and the market value of the held-to-maturity investments.

At March 29, 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 asset purchase agreement dated March 14, 2003. The Company is accounting for the shares in accordance with SFAS No. 115 as available-for-sale securities and as a result, the shares are recorded at fair value.

At December 31, 2002 and March 29, 2003, the Company's cash and cash equivalents and investments consisted of the following:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Loss	Estimated Fair Value
<b>December 31, 2002</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>December 31, 2002 Available-for-Sale</b>				
Investment in equity securities	\$ 200,160	\$ 285,390	\$	\$ 485,550
<b>March 29, 2003</b>				
Cash and Cash Equivalents:				
Cash	\$ 13,062,243	\$	\$	\$ 13,062,243
Debt securities	3,600,000			3,600,000

Edgar Filing: GENOME THERAPEUTICS CORP - Form 10-Q

Total cash and cash equivalents	\$ 16,662,243	\$	\$	\$ 16,662,243
<b>Investments Held-to-Maturity:</b>				
Short-term marketable securities	\$ 23,109,280	\$ 47,476	\$ (1,875)	\$ 23,154,881
Long-term marketable securities	2,944,058	22,467		2,966,525
Total investments	\$ 26,053,338	\$ 69,943	\$ (1,875)	\$ 26,121,406
<b>March 29, 2003 Available-for-Sale</b>				
Investment in equity securities	\$ 425,089	\$ 280,395	\$	\$ 705,848



---

**Table of Contents****(5) LONG-TERM OBLIGATIONS**

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 may be converted 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 is December 31, 2004, provided, that if at any time on or after December 31, 2003, the Company maintains a net cash balance (i.e., cash and cash equivalents less obligations for borrowed money bearing interest) of less than \$35 million, then the holders of the convertible notes payable can require that all or any part of the outstanding principal balance of the convertible notes payable plus all accrued but unpaid interest be repaid. Interest on the convertible notes payable accrues at 6% annually and the interest is payable, in cash or in stock, semi-annually on June 30 and December 31 of each year. As of March 29, 2003, two interest payments on the convertible notes payable had become due and were paid by issuing 494,093 shares of the Company's common stock to the holders of the notes payable, of which 120,986 and 373,107 shares were issued in July 2002 and January 2003, respectively. 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 is exercisable at the time the convertible notes payable are converted or if certain other redemptions or repayments of the convertible notes payable occur and will terminate 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 will be 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. This amount is included in deferred issuance costs and will be amortized to interest expense over the term of the convertible notes payable. As of March 29, 2003, this warrant had not been issued.

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 (1.80% at March 29, 2003) plus 1.50%. The Company is required to maintain certain financial covenants pertaining to minimum cash balances. As of March 29, 2003, \$2.3 million was outstanding under the loan agreement, and the Company was in compliance with all of the covenants.

**(6) 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.

Edgar Filing: GENOME THERAPEUTICS CORP - Form 10-Q

The Company expended approximately \$3,090,000 and \$3,616,000 during the thirteen-week periods ended March 30, 2002 and March 29, 2003, respectively, which, in each case, consisted primarily of clinical development expenses.

**Table of Contents**

**(7) ALLIANCES BIOPHARMACEUTICAL**

**(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 March 29, 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 thirteen-week periods ended March 30, 2002 and March 29, 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 *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 milestone payments through March 29, 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.

## Edgar Filing: GENOME THERAPEUTICS CORP - Form 10-Q

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 \$126,000 and \$0 in revenue during the thirteen-week period ended March 30, 2002 and March 29, 2003, respectively.

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

**Table of Contents**

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 this 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 \$42.4 million has been received through March 29, 2003.

Under the December 1996 agreement, the Company recognized approximately \$1,730,000 and \$115,000 in revenue during the thirteen-week period ended March 30, 2002 and March 29, 2003, 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, 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 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 March 29, 2003.

Under the September 1997 agreement, the Company recognized approximately \$6,000 and \$0 in revenue during the thirteen-week period ended March 30, 2002 and March 29, 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

## Edgar Filing: GENOME THERAPEUTICS CORP - Form 10-Q

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 PathoGenom<sup>TM</sup> 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 \$4.4 million has been received through March 29, 2003.

**Table of Contents**

The Company recognized approximately \$297,000 in revenue during both thirteen-week periods ended March 30, 2002 and March 29, 2003, 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 \$9.7 million has been received through March 29, 2003.

The Company recognized approximately \$261,000 and \$268,000 in revenue during the thirteen-week period ended March 30, 2002 and March 29, 2003, respectively, which consisted of alliance research revenue and amortization of the up-front license fees.

(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.

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 \$1.0 million has been received through March 29, 2003.

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

Edgar Filing: GENOME THERAPEUTICS CORP - Form 10-Q

increased royalties on sales or participate in profits from product sales in the U.S. and Canada.

The Company recognized approximately \$769,000 in revenue during the thirteen week period ended March 29, 2003, which consisted of alliance research revenue and amortization of the up-front license fee.



**Table of Contents**

**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 and 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 or 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 the Company's Annual Report on Form 10-K for the year ended December 31, 2002 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, development and commercialization of pharmaceutical and diagnostic products. Our strategic goal is to directly participate in the commercialization of products that are used primarily in hospitals. For diseases treated by

## Edgar Filing: GENOME THERAPEUTICS CORP - Form 10-Q

larger physician audiences, we seek to discover, develop and commercialize products through alliances with major pharmaceutical companies.

We have nine established product development programs. We are managing the development and commercialization of our lead product candidate, Ramoplanin, in the United States and Canada. This product is in a Phase III clinical trial for the prevention of bloodstream infections caused by vancomycin-resistant enterococci (VRE) and a Phase II trial for the treatment of patients with Clostridium difficile-associated diarrhea (CDAD). We have seven product discovery and development alliances with pharmaceutical companies including Amgen, AstraZeneca, bioMerieux, Schering-Plough and Wyeth. In addition, we have a portfolio of internal drug discovery programs. 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 the our continued evolution into a biopharmaceutical company, this business unit was divested in March 2003.

---

**Table of Contents**

We concentrate our product discovery, development and commercialization efforts in two principal areas:

- (i) infectious diseases caused by bacterial and fungal pathogens, and
- (ii) human diseases believed to have a significant genetic component

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.

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. In August 1995, we entered into an alliance with AstraZeneca to develop pharmaceutical, vaccine and diagnostic products effective against gastrointestinal infections or any other disease caused by *Helicobacter pylori* (*H. pylori*). In August 1999, the contract research under the alliance concluded and the program transitioned into AstraZeneca's pipeline. We are entitled to receive additional milestone payments and royalties based upon the development by AstraZeneca of any products from the research alliance. In December 1995, we entered into an alliance with Schering-Plough. Under this alliance, Schering-Plough can use our *Staphylococcus aureus* (*Staph. aureus*) genomic database to identify new gene targets for the development of novel antibiotics. In March 2002, we had completed our research obligations under this alliance and had turned over validated drug targets and assays to Schering-Plough for high-throughput screening. In December 1996, we entered into our second research alliance with Schering-Plough to identify genes and associated proteins that Schering-Plough can utilize to develop new pharmaceuticals for treating asthma. In December 2002, we had completed our research obligations under this alliance and the research program has advanced into high-throughput screening at Schering-Plough to identify drug candidates. In September 1997, we established our third research alliance with Schering-Plough for the development of new pharmaceutical products to treat fungal infections. In March 2002, we had completed our research obligations under this alliance and had turned over validated drug targets and assays to Schering-Plough for high-throughput screening. In September 1999, we entered into a strategic alliance with bioMerieux to develop, manufacture and sell in vitro pathogen diagnostic products for human clinical and industrial applications. As part of the strategic alliance, bioMerieux purchased a subscription to our PathoGenome™ Database and made an equity investment in the Company. In December 1999, we entered into a strategic alliance with Wyeth to develop drugs based on our genetic research to treat osteoporosis. In December 2002, we entered into a strategic alliance with Amgen, Inc. to identify and develop novel therapeutic agents for bone diseases, including osteoporosis.

In 2002 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 a cash up-front payment 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.



## **Table of Contents**

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 \$700,000 in the first quarter of 2003, of which approximately \$130,000 was related to the transfer of assets to Agencourt and approximately \$570,000 associated with the reduction in work force, such as severance costs and outplacement services.

We receive payments under our biopharmaceutical business 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 March 29, 2003, we had an accumulated deficit of approximately \$134.5 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.

## **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. Genomics Services revenues consist of government grants, fees received from custom gene sequencing and analysis services and subscription fees from the PathoGenome™ Database. Revenues from contract research, government grants, the PathoGenome™ Database subscription fees, 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. License fees are recognized ratably over the performance period in accordance with Staff Accounting Bulletin (SAB) No. 101, Revenue Recognition. Milestone payments will be recognized upon achievements of the milestone as long as the milestone is deemed to be substantive and we have no other performance obligations related to the milestone. Unbilled costs and fees represent revenue recognized prior to billing. Deferred revenue represents amounts received prior to revenue recognition.

*Clinical Trial Expense Accrual*

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. To

## **Table of Contents**

date, these adjustments have not been material to our financial statements, and we believe that the estimates that we made as of March 29, 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 March 30, 2002 and March 29, 2003***

#### *Revenues*

Total revenues decreased 56% from \$6,165,000 for the thirteen-week period ended March 30, 2002 to \$2,739,000 for the thirteen-week period ended March 29, 2003. Biopharmaceutical revenues decreased 40% from \$2,434,000 for the thirteen-week period ended March 29, 2002 to \$1,454,000 for the thirteen-week period ended March 30, 2003. The decrease in biopharmaceutical revenue reflects lower sponsored research revenue as a result of the completion last year of our research obligations under our three alliances with Schering-Plough.

Revenues from Genomics Services decreased 66% from \$3,731,000 for the thirteen-week period ended March 30, 2002 to \$1,285,000 for the thirteen-week period ended March 29, 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 19% from \$13,317,000 for the thirteen-week period ended March 30, 2002 to \$10,842,000 for the thirteen-week period ended March 29, 2003. Cost of services decreased 44% from \$3,414,000 for the thirteen-week period ended March 30, 2002 to \$1,903,000 for the thirteen-week period ended March 29, 2003 primarily due to decreased costs and expenses associated with the reduction of our activities under our Genomics Services business, as described in the above paragraph. Cost of revenues, as a percentage of Genomics Services revenue, increased from 92% for the thirteen week period ended March 30, 2002 to 148% for the thirteen week period ended March 29, 2003 primarily due to the allocation of fixed overhead expenses to this business unit.

Research and development expenses include internal research and development, research funded pursuant to arrangements with our strategic alliance partners, as well as clinical development costs and expenses. Research and development expenses decreased 14% from \$7,846,000 for the thirteen-week period ended March 30, 2002 to \$6,715,000 for the thirteen-week period ended March 29, 2003. This planned decrease was primarily due to a reduction in internal early-stage target identification research programs totaling \$1,020,000, decrease in costs and expenses associated with the decrease in biopharmaceutical revenue of approximately \$635,000, partially offset by higher expenses incurred in the clinical development of Ramoplanin of approximately \$524,000.

## Edgar Filing: GENOME THERAPEUTICS CORP - Form 10-Q

Selling, general and administrative expenses increased 8% from \$2,057,000 for the thirteen-week period ended March 30, 2002 to \$2,224,000 for the thirteen-week period ended March 29, 2003 primarily reflecting an expansion in the area of corporate development.

### *Other Income and Expense*

Interest income decreased 56% from \$531,000 for the thirteen-week period ended March 30, 2002 to \$232,000 for the thirteen-week period ended March 29, 2003 reflecting lower interest rate yields from investments, as well as a decrease in funds available for investment.

Interest expense increased 229% from \$216,000 for the thirteen-week period ended March 30, 2002 to \$710,000 for the thirteen-week period ended March 29, 2003. The increase in interest expense reflects interest expense of \$158,000 associated with the March 2002 sale of convertible notes payable, which historically has been paid out in the form of shares in our common stock, and approximately \$212,000 related to the amortization of



## **Table of Contents**

deferred issuance costs and warrants issued in connection with these convertible notes payable. The increase in interest expense also reflects approximately \$124,000 of interest expense related to equipment financing arrangements.

For the thirteen-week period ended March 30, 2002, we recorded a gain on the sale of fixed assets of approximately \$53,000. For the thirteen-week period ended March 29, 2003, we recorded a loss on the sale of fixed assets of approximately \$130,000 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 March 29, 2003, we had cash, cash equivalents and short-term and long-term marketable securities of approximately \$43,421,000. 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 convertible notes payable may be converted into shares of our 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 is December 31, 2004, provided, that if any time on or after December 31, 2003 we maintain a net cash balance (i.e., cash and cash equivalents less obligations for borrowed money bearing interest) of less than \$35 million, then the holders of the convertible notes payable can require that all or any part of the outstanding principal balance of the notes payable plus all accrued but unpaid interest be repaid. Interest on the notes payable accrues at 6% annually and the interest is payable, in cash or in stock, semi-annually on June 30 and December 31 of each year. As of December 31, 2002, two interest payments on the convertible notes payable had become due and were paid by issuing 494,083 shares of our common stock to the holders of the notes payable, of which 120,986 and 373,107 shares were issued in July 2002 and January 2003, respectively. 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 is exercisable at the time the convertible notes payable are converted or if certain other redemptions or repayments of the convertible notes payable occur and will terminate upon the earlier of four years from date of such conversion or December 31, 2008. The warrant was valued, using the Black-Scholes option pricing model, at \$1,736,000. The amount was recorded as a discount to long-term debt and will be amortized to interest expense over the term of the convertible notes payable. 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. This amount is included in deferred issuance costs and will be amortized to interest expense over the term of the convertible notes payable.

We have a loan agreement under which we have financed certain office and laboratory equipment and leasehold improvements. We had approximately \$2,333,000 outstanding under this borrowing arrangement at March 29, 2003. This amount is repayable over the next 23 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 March 29, 2003.

Our operating activities used cash of approximately \$5,904,000 and \$5,769,000 for the thirteen-week periods ended March 30, 2002 and March 29, 2003, respectively, due primarily to an increase in our net loss, unbilled costs and fees and deferred revenue and a decrease in accounts payable and accrued expenses. These uses of cash were partially offset by a decrease in interest receivable, accounts receivable, as well as an increase in clinical trial expense accrual.

## Edgar Filing: GENOME THERAPEUTICS CORP - Form 10-Q

Our investing activities provided cash of approximately \$7,163,000 and \$10,113,000 for the thirteen-week periods ended March 30, 2002 and March 29, 2003, respectively, through the conversion of marketable securities to cash and cash equivalents and proceeds received from the sale of property and equipment, partially offset by purchases of marketable securities, equipment and additions to leasehold improvements.

## **Table of Contents**

Capital expenditures totaled \$106,000 for the thirteen-week period ended March 29, 2003 primarily consisting of purchases of laboratory and computer equipment. We currently estimate that we will acquire no more than \$500,000 in capital equipment in 2003 consisting of laboratory and computer equipment, and additions to leasehold improvements.

Our financing activities provided cash of approximately \$16,700,000 for the thirteen-week period ended March 30, 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 \$2,066,000. Our financing activities used cash of approximately \$1,910,000 for the thirteen week period ended March 29, 2003 primarily due to payments of long-term obligations of \$2,170,000, partially offset by proceeds received from the exercise of stock options and employee stock purchase plan totaling approximately \$260,000.

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 \$10-15 million in clinical development expenditures during 2003.

We believe that our existing capital resources are adequate for approximately two years under our current rate of investment in research and development. However, in the event that we are obligated to repay our convertible loan at the end of 2003, we believe that our capital resources are adequate for approximately fourteen 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 costs, including the formation of additional alliances and partnerships aimed at reducing unsponsored research.

We plan to seek additional funding in the next 12 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.

**Table of Contents**

**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. There have been no material changes in the first three months of 2003 to such risks or our management of such risks.

**ITEM 4: CONTROLS AND PROCEDURES**

Within the 90 days prior to the date of filing this Quarterly Report on Form 10-Q, we carried out an evaluation, under the supervision and with the participation of our management, including the Chief Executive Officer and the Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-14. Based upon that evaluation, the Chief Executive Officer and the Chief Financial Officer concluded that our disclosure controls and procedures are effective in timely alerting them to material information relating to the Company required to be included in our periodic SEC filings. Subsequent to the date of that evaluation, there have been no significant changes in our internal controls or in other factors that could significantly affect internal controls, nor were any corrective actions required with regard to significant deficiencies and material weaknesses.

**Table of Contents**

**PART II**

**Item 1. *Legal Proceedings***

None

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

None

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

None

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

None

**Item 5. *Other Information***

None

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

(a) Exhibits:

Edgar Filing: GENOME THERAPEUTICS CORP - Form 10-Q

- 10.1 Retirement Agreement with Robert J. Hennessey.
- 10.2 Amended and Restated Employment Agreement with Stephen Cohen.
- 10.3 Amended and Restated Employment Agreement with Richard Labaudiniere.
- 10.4 Employment Agreement with Martin D. Williams.
- 99.1 Certification of the Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act.
- 99.2 Certification of the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act.

**Table of Contents**

99.2 Certification of the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act.

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

Report on Form 8-K filed January 2, 2003 to report that the Company has established an alliance with Amgen Inc. for the identification and development of novel therapeutics agents for bone diseases, including osteoporosis.

**Table of Contents**

**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

Stephen Cohen,

Senior Vice President & Chief Financial Officer

(Principal Financial Officer)

May 13, 2003



**Table of Contents**

**GENOME THERAPEUTICS CORP. AND SUBSIDIARY**

**CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Steven M. Rauscher, President and Chief Executive Officer of Genome Therapeutics Corp., certify that:

- 1) I have reviewed this quarterly report on Form 10-Q of Genome Therapeutics Corp.;
- 2) Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
- 3) Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
- 4) The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
  - c) Presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
- 5) The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

Edgar Filing: GENOME THERAPEUTICS CORP - Form 10-Q

- 6) The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 13, 2003

/s/ Steven M. Rauscher

Steven M. Rauscher

President & Chief Executive Officer

**Table of Contents**

**GENOME THERAPEUTICS CORP. AND SUBSIDIARY**

**CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Stephen Cohen, Senior Vice President and Chief Financial Officer of Genome Therapeutics Corp., certify that:

- 1) I have reviewed this quarterly report on Form 10-Q of Genome Therapeutics Corp.;
- 2) Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
- 3) Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
- 4) The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and
  - c) Presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
- 5) The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
- 6) The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation,

Edgar Filing: GENOME THERAPEUTICS CORP - Form 10-Q

including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 13, 2003

/s/ Stephen Cohen

Stephen Cohen

Senior Vice President & Chief Financial Officer

**Table of Contents**

**GENOME THERAPEUTICS CORP. AND SUBSIDIARY**

**EXHIBIT INDEX**

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
10.1	Retirement Agreement with Robert J. Hennessey.
10.2	Amended and Restated Employment Agreement with Stephen Cohen.
10.3	Amended and Restated Employment Agreement with Richard Labaudiniere.
10.4	Employment Agreement with Martin D. Williams.
99.1	Certification of the Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act.
99.2	Certification of the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act.