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GENOME THERAPEUTICS CORP

Form 10-Q

November 13, 2001

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 10-Q

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

For the Quarterly Period Ended: September 29, 2001

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

04-2297484

(STATE OR OTHER JURISDICTION  
OF INCORPORATION OR ORGANIZATION)

(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

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

COMMON STOCK	22,765,285
-----	-----
\$.10 PAR VALUE	Outstanding November 9, 2001
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Genome Therapeutics Corp. and Subsidiary

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GENOME THERAPEUTICS CORP. AND SUBSIDIARY  
CONSOLIDATED CONDENSED BALANCE SHEETS

	December 31, 2000	September 29, 2001 (Unaudited)
Assets		
Current Assets:		
Cash and cash equivalents	\$10,095,817	\$26,147,252
Marketable securities	51,743,917	31,327,186
Interest receivable	1,466,808	870,756
Accounts receivable	827,106	288,446
Unbilled costs and fees	796,072	422,154
Prepaid expenses and other current assets	900,547	1,039,985
	65,830,267	60,095,779
Equipment, furniture and leasehold improvements, at cost:		
Laboratory and scientific equipment	18,823,063	20,559,610
Leasehold improvements	8,302,308	8,759,588
Equipment and furniture	1,134,320	1,267,854
	28,259,691	30,587,052
Less accumulated depreciation and amortization	15,225,148	18,010,641

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	13,034,543	12,576,411
Restricted cash	200,000	200,000
Long-term marketable securities	10,970,153	14,850,174
Other assets	216,041	234,723
Total assets	\$90,251,004	\$87,957,087
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	\$1,296,511	\$1,536,313
Accrued expenses	3,712,757	3,673,659
Deferred revenue	4,720,234	2,588,564
Current maturities of long-term obligations	4,499,696	3,917,290
Total current liabilities	14,229,198	11,715,826
Long-term obligations, net of current maturities	3,334,354	2,587,860
Stockholders' equity	72,687,452	73,653,401
Total liabilities and stockholders' equity	\$90,251,004	\$87,957,087

See Notes to Consolidated Condensed Financial Statements.

GENOME THERAPEUTICS CORP. AND SUBSIDIARY  
CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

	Four Week Period Ended June 23, 2001	Thirteen Week Period Ended Sept. 23, 2000    Sept. 29, 2001	
Revenues:			
Contract research, licenses, milestones and subscription fees	\$ 7,226,276	\$ 5,924,851	\$ 7,378,035
Costs and Expenses:			
Research and development	2,337,214	6,505,355	9,880,970
Selling, general and administrative	863,752	1,711,451	2,559,004
Total costs and expenses	3,200,966	8,216,806	12,439,974
Income (Loss) from operations	4,025,310	(2,291,955)	(5,061,939)
Interest income	303,975	1,180,363	1,055,631
Interest expense	(80,568)	(210,751)	(174,269)
Net interest income	223,407	969,612	881,362

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Net Income (loss)	4,248,717	(\$1,322,343)	(\$4,180,577)
Net Income (Loss) per Common Share:			
Basic	\$0.19	(\$0.06)	(\$0.18)
Diluted	\$0.18	(\$0.06)	(\$0.18)
Weighted average common shares outstanding:			
Basic	22,484,080	22,163,366	22,685,660
Diluted	23,850,825	22,163,366	22,685,660

See Notes to Consolidated Condensed Financial Statements.

GENOME THERAPEUTICS CORP. AND SUBSIDIARY  
CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

	Four Week Period Ended June 23, 2001	Thir Septe
Cash Flows from Operating Activities:		
Net Income (loss)	\$4,248,717	(\$3
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	372,775	3
Loss on disposal of fixed assets	868	
Stock-based compensation expense	41,307	
Changes in assets and liabilities:		
Interest receivable	(85,894)	
Accounts receivable	(102,585)	
Unbilled costs and fees	188,028	1
Prepaid expenses and other current assets	127,810	
Accounts payable	(416,932)	
Accrued expenses	151,164	
Deferred revenue	(1,090,465)	(1
Total adjustments	(813,924)	5
Net cash provided by operating activities	3,434,793	1
Cash Flows from Investing Activities:		
Purchases of marketable securities	(6,044,095)	(39
Maturities of marketable securities	2,886,000	24
Purchases of equipment, furniture and leasehold improvements	(139,494)	
(Increase) decrease in other assets	2,875	

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Net cash (used in) provided by investing activities	(3,294,714)	(14)
Cash Flows from Financing Activities:		
Proceeds from sale of common stock	0	44
Proceeds from exercise of stock options	43,084	3
Proceeds from employee stock purchase plan	0	
Payments on long-term obligations	(328,844)	(3)
Net cash (used in) provided by financing activities	(285,760)	44
Net Increase (Decrease) in Cash and Cash Equivalents	(145,681)	31
Cash and Cash Equivalents, at beginning of period	20,201,979	5
Cash and Cash Equivalents, at end of period	\$20,056,298	\$36
Supplemental Disclosure of Cash Flow Information:		
Interest paid during period	\$80,568	
Income taxes paid during period	\$12,500	
Supplemental Disclosure of Non-cash Investing and Financing Activities:		
Equipment acquired under capital lease obligations	\$0	\$3

See Notes to Consolidated Condensed Financial Statements.

NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS (UNAUDITED)

1. BASIS OF PRESENTATION

The consolidated condensed financial statements included herein have been prepared by the Company, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission. In the opinion of management, the unaudited consolidated condensed financial statements have been prepared on the same basis as the audited consolidated financial statements and include all adjustments (consisting only of normal recurring entries) necessary for a fair presentation of interim period results. Certain information and footnote disclosures normally included in the 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 Form 10-K, which was filed with the Securities and Exchange Commission on November 22, 2000.

On July 24, 2001 the Board of Directors of Genome Therapeutics Corp. approved a change of the Company's fiscal year end from August 31 to December 31, as of the fiscal year ended December 31, 2000. A transition report on Form 10-Q covering the transition period from September 1, 2000 through December 31, 2000, was filed with the Securities and Exchange Commission on September 7, 2001; this filing included financial statements restated to provide financial

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information for the four months ended December 31, 2000 and 1999.

The Company has included financial information for the four week period ended June 23, 2001 in this Form 10-Q filing since this information was not included in past quarterly filings with the Securities and Exchange Commission due to the change in the Company's fiscal year end, as mentioned above.

### 2. REVENUE RECOGNITION

Revenues consist of contract research, non-refundable license fees, milestone payments and subscription fees from the PathoGenome™ Database. These revenues are derived from alliances with pharmaceutical companies, government grants and contracts, and fees received from custom gene sequencing and analysis. The Company follows the provisions of Staff Accounting Bulletin (SAB) No. 101, Revenue Recognition. In accordance with SAB No. 101, revenues from contract research derived from alliances with pharmaceutical companies, from government grants and contracts, and from custom gene sequencing and analysis are recognized over the respective contract periods as the services are provided. Non-refundable license fees are recognized ratably over the life of the alliance. Subscription fees from the PathoGenome Database are recognized ratably over the life of the subscription. Milestone payments, that are deemed to be substantive from research and development alliances, are recognized when they are achieved. Unbilled costs and fees represent revenue recognized prior to billing. Deferred revenue represents amounts billed and received prior to revenue recognition.

### 3. NET LOSS PER COMMON SHARE

The Company applies Statement of Financial Accounting Standards (SFAS) No. 128, Earnings per Share, which establishes standards for computing and presenting earnings per share. Basic earnings per share was determined by dividing net income by the weighted average common shares outstanding during the period. Diluted earnings per share was determined by dividing net income by the weighted average common and common equivalent shares outstanding during the period using the treasury stock method. Antidilutive securities which consist of stock options, restricted stock and directors' deferred stock that were not included in diluted net loss per common share were 3,328,233 and 2,422,116 at September 29, 2001 and September 23, 2000, respectively.

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### 4. CASH, CASH EQUIVALENTS AND MARKETABLE SECURITIES

The Company applies SFAS No. 115, Accounting for Certain Investments in Debt and Equity Securities. At December 31, 2000 and September 29, 2001, the Company's cash equivalents and marketable securities 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 three months or less. Marketable securities are investment securities with original maturities of greater than three months. Cash equivalents are carried at cost, which approximates market value, and consist of money market funds, repurchase agreements and debt securities. Marketable securities are recorded at amortized cost, which approximates market value. The Company has not recorded any realized gains or losses on its marketable securities. Marketable securities consist of commercial paper and U.S. government debt securities. The average maturity of the Company's marketable securities is approximately 9 months at September 29, 2001.

At December 31, 2000 and September 29, 2001, the Company's cash, cash

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equivalents and marketable securities consisted of the following:

	December 31, 2000	September 29, 2001
	-----	-----
Cash and Cash Equivalents:		
Cash.....	\$ 9,245,817	\$24,147,252
Debt securities.....	850,000	2,000,000
	-----	-----
Total cash and cash equivalents.....	\$10,095,817	\$26,147,252
	-----	-----
Marketable Securities:		
Short-term securities.....	\$51,743,917	\$31,327,186
Long-term securities.....	10,970,153	14,850,174
	-----	-----
Total marketable securities.....	\$62,714,070	\$46,177,360
	-----	-----

The Company has \$200,000 in restricted cash in connection with certain long-term obligations at December 31, 2000 and September 29, 2001 (see Note 9).

5. 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 significant 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, cash equivalents and marketable securities balances with several nonaffiliated institutions.

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

	Number of Significant Customers	Percentage of Total Revenues		
		A	B	C
	-----	---	---	---
Thirteen week period ended:				
September 23, 2000.....	2	33%	35%	6
September 29, 2001.....	2	53%	31%	5
Thirty-nine week period ended:				
September 23, 2000.....	2	34%	35%	6
September 29, 2001.....	3	37%	26%	23

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

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percentage of the Company's total accounts receivable:

As of:	Number of Significant Customers	Percentage of Total Accounts Receivable			
		A	B	C	D
September 23, 2000.....	2	37%	55%	0%	0
September 29, 2001.....	3	34%	6%	15%	19

### 6. USE OF ESTIMATES IN THE PREPARATION OF FINANCIAL STATEMENTS

The preparation of financial statements in conformity with generally accepted accounting principles 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 financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

### 7. COMPREHENSIVE LOSS

The Company applies SFAS No. 130, Reporting Comprehensive Income. SFAS No. 130 requires disclosure of all components of comprehensive income on an annual and interim basis. Comprehensive income is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. The Company's total comprehensive net income (loss) for the four week period ended June 23, 2001 and for the thirteen and thirty-nine week periods ended September 23, 2000 and September 29, 2001 were the same as reported net income (loss) for those periods.

### 8. SEGMENT REPORTING

The Company applies 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 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 one operating segment. As a result, the financial information disclosed herein represents all of the material financial information related to the Company's principal operating segment. All of the Company's revenues are generated in the United States and all of its assets are located in the United States.

### 9. LONG-TERM OBLIGATIONS

On February 23, 2000, the Company entered into an equipment line of credit under which it may finance up to \$4,000,000 of laboratory, computer and office equipment. On December 18, 2000, the Company increased the line of credit by \$2,712,000 to \$6,712,000. The Company, at its discretion, can enter into either



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an operating or capital lease. Borrowings under operating leases are payable in 24 monthly installments and capital leases are payable in 36 monthly installments. As of

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September 29, 2001, the Company has entered into \$256,000 in operating leases and \$6,456,000 in capital leases. The interest rates under the capital leases range from 7.50% to 10.37%. In addition, the Company had entered into other capital lease arrangements under which it financed approximately \$15,060,000 of laboratory, computer and office equipment, as well as facility renovations. These leases are payable in 36 to 48 monthly installments from date of initiation. Interest rates range from 7.63% to 10.28%. Under several agreements, we are required to maintain certain financial ratios pertaining to minimum cash balances, tangible net worth and debt service coverage. As of September 29, 2001, the Company was in compliance with all of these covenants. The Company had no additional borrowing capacity under these capital lease agreements at September 29, 2001.

### 10. ALLIANCES

#### (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 to further develop and annotate the Company's *H. pylori* genomic sequence database, identify therapeutic and vaccine targets and develop appropriate biological assays. In August 1999, the Company successfully concluded its portion of the research alliance and transitioned the program to AstraZeneca for pre-clinical testing.

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 received \$13.5 million in license fees, expense allowances, milestone payments and research funding under the Astra agreement through September 29, 2001.

The Company will also be entitled to receive royalties on Astra's sale of products protected by the claims of patents licensed exclusively to Astra by the Company pursuant to the agreement or the discovery of which was enabled in a significant manner by the genomic database licensed to Astra by the Company. The Company has the right, under certain circumstances, to convert Astra's license to a nonexclusive license in the event that Astra is not actively pursuing commercialization of the technology.

For the disclosed thirty-nine week periods ended September 29, 2001 and September 23, 2000, the Company recorded revenue of \$0 and \$6,000, respectively, under this agreement.

#### (B) SCHERING-PLOUGH

In December 1995, the Company entered into a strategic alliance and license agreement with Schering Corporation and Schering-Plough Ltd. (collectively,

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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 also granted Schering-Plough a nonexclusive license to use the Company's bioinformatics systems for Schering-Plough's internal use in connection with the genomic databases licensed to Schering-Plough under the agreement and other genomic databases Schering-Plough develops or acquires. The Company also 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.

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Under this agreement, Schering-Plough paid an initial license fee and will fund the research program through December 31, 2001. Under this agreement, Schering-Plough agreed to pay the Company a minimum of \$21.9 million in an up-front license fee, research funding and milestone payments. Subject to the achievement of additional product development milestones, Schering-Plough agreed to pay the Company up to an additional \$24 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 by the Company 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 from the Company. A total of \$21.3 million had been received through September 29, 2001.

For the thirteen-week periods ended September 29, 2001 and September 23, 2000, the Company recorded revenue of \$426,000 and \$441,000, respectively, under this agreement, which consisted of contract research revenue.

For the thirty-nine week periods ended September 29, 2001 and September 23, 2000, the Company recorded revenue of \$1,275,000 and \$1,420,000, respectively, under this agreement, which consisted of contract research revenue.

In December 1996, the Company entered into its second strategic alliance and license 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 will employ 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, Schering-Plough paid an initial license fee and an expense allowance to the Company. Schering-Plough agreed to fund the research program through at least December 2001. In addition, upon completion of certain scientific developments, Schering-Plough will make milestone payments, as well as pay royalties based upon sales of therapeutics products developed from this collaboration. If all milestones are met and the research program continues for its full term, total payments to the Company will approximate \$75.9 million,

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excluding royalties. Of the total potential payments, approximately \$31.4 million represents license fees and research payments, and \$44.5 million represent milestone payments based on achievement of research and product development milestones. A total of \$33.3 million has been received through September 29, 2001.

For the thirteen-week periods ended September 29, 2001 and September 23, 2000, the Company recorded revenue of \$1,499,000 and \$1,145,000, respectively, under this agreement, which consisted of contract research revenue.

For the thirty-nine week periods ended September 29, 2001 and September 23, 2000, the Company recorded revenue of \$3,607,000 and \$3,492,000, respectively, under this agreement, which consisted of contract research revenue and milestone payments.

On September 1997, the Company entered into a third strategic alliance and license agreement with Schering-Plough to use genomics to discover and develop new pharmaceutical products to treat fungal infections.

Under the agreement, the Company will employ 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.

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Schering-Plough will receive exclusive access to the genomic information developed in the alliance related to two fungal pathogens, *Candida albicans* and *Aspergillus fumigatus*. Schering-Plough will also receive exclusive worldwide right 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 December 2001. If all milestones are met and the research program continues for its full term, total payments to the Company will approximate \$32.7 million, excluding royalties. Of the total potential payments, \$9.7 million represents contract research payments and \$23.0 million represents milestone payments based on achievement of research and product development milestones. A total of \$12.2 million has been received through September 29, 2001. Additionally, the Company entered into a subscription agreement with Schering-Plough to provide Schering-Plough with nonexclusive access to the Company's proprietary genome sequence database, PathoGenome, and associated information relating to microbial organisms (see Note 11).

For the thirteen-week periods ended September 29, 2001 and September 23, 2000, the Company recorded revenue of \$356,000 and \$482,000, respectively, under this agreement, which consisted of contract research revenue.

For the thirty-nine week periods ended September 29, 2001 and September 23, 2000, the Company recorded revenue of \$1,169,000 and \$1,530,000, respectively, under this agreement, which consisted of contract research revenue.

### (C) NATIONAL HUMAN GENOME RESEARCH INSTITUTE

In July 1999, the Company was named as one of the nationally funded DNA sequencing centers of the international Human Genome Project. The Company is participating as part of an international consortium in a full-scale effort to sequence the human genome. The Company is entitled to receive research and development funding from the National Human Genome Research Institute (NHGRI) of up to \$17.4 million over a forty-four month period, of which \$14.1 million is appropriated through February 2002.

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In October 1999, the NHGRI named the Company as a pilot center to the Mouse Genome Sequencing Network. The Company is entitled to receive \$13.4 million in funding over three years with respect to this agreement, of which \$9.3 million is appropriated through November 2001. In August 2000, the Company was named one of two primary centers for the Rat Sequencing Program from NHGRI. As part of the agreement, we will use remaining funding under the mouse award, as well as a portion of the remaining funding under the human award, to participate in this rat genome initiative.

For the thirteen-week periods ended September 29, 2001 and September 23, 2000, the Company recorded revenue of \$3,551,000 and \$1,804,000, respectively, under these agreements. For the thirty-nine week periods ended September 29, 2001 and September 23, 2000, the Company recorded revenue of \$9,191,000 and \$6,087,000, respectively, under these agreements.

Funding under our government grants and research contracts is subject to appropriation each year by the U.S. Congress and can be discontinued or reduced at any time. In addition, we cannot be certain that we will receive additional grants or contracts in the future.

### (D) BIOMERIEUX ALLIANCE

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 (see Note 11), 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 ratably over the four-year term of the agreement.

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For the thirteen-week periods ended September 29, 2001 and September 23, 2000, the Company recorded revenue of \$297,000 for each period under this agreement, which consisted of contract research revenue and amortization of an up-front license fee. For the thirty-nine week periods ended September 29, 2001 and September 23, 2000, the Company recorded revenue of \$900,000 for each period under this agreement, which consisted of contract research revenue and amortization of an up-front license fee. A total of \$3.2 million has been received through September 29, 2001.

### (E) WYETH-AYERST LABORATORIES

In December 1999, the Company entered into a strategic alliance with Wyeth-Ayerst Laboratories 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-Ayerst'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-Ayerst paid the Company an up-front license fee, and funded a multi-year research program, which includes milestone payments and royalties on sales of therapeutics products developed from this alliance. If the research program continues for its full term and substantially all of the milestone payments are met, total payments to

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the Company, excluding royalties, would exceed \$118 million.

The Company recorded revenue of \$375,000 for both thirteen-week periods ended September 29, 2001 and September 23, 2000, under this agreement, which consisted of contract research revenue and amortization of an up-front license fee.

For the thirty-nine week period ended September 29, 2001, the Company recorded revenue of \$6,125,000 under this agreement, which consisted of contract research revenue, amortization of an up-front license fee and a \$5.0 million milestone payment. For the thirty-nine week period ended September 23, 2000, the Company recorded revenue of \$1,125,000 under this agreement, which consisted of contract research revenue and amortization of an up-front license fee. A total of \$7.8 million has been received through September 29, 2001.

### 11. DATABASE SUBSCRIPTIONS

The Company has entered into a number of PathoGenome™ Database subscriptions. The database subscriptions provide nonexclusive access to the Company's proprietary genome sequence database, PathoGenome Database, and associated information relating to microbial organisms. These agreements call for the Company to provide periodic data updates, analysis tools and software support. Under the subscription agreements, the customer pays an annual subscription fee and will pay royalties on any molecules developed as a result of access to the information provided by the PathoGenome Database. The Company retains all rights associated with protein therapeutic, diagnostic and vaccine use of bacterial genes or gene products.

For the thirteen-week periods ended September 29, 2001 and September 23, 2000, the Company recorded revenue of \$412,000 and \$950,000, respectively, under these agreements. For the thirty-nine week periods ended September 29, 2001 and September 23, 2000, the Company recorded revenue of \$2,071,000 and \$3,012,000, respectively, under these agreements.

### 12. PRODUCT DEVELOPMENT

On October 8, 2001, subsequent to quarter-end, the Company had acquired an exclusive license in the United States and Canada for a novel antibiotic, Ramoplanin, from Biosearch Italia S.p.A

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(Biosearch Italia). The Company will assume responsibility for the product development in the United States of Ramoplanin, currently in Phase III clinical trials. The agreement provides the Company with exclusive rights to develop and market oral Ramoplanin in the U.S. and Canada. Biosearch Italia 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 the agreement, the Company has paid Biosearch Italia 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 to purchasing bulk material from Biosearch Italia, the Company will fund the completion of clinical trials and pay a royalty on product sales. The combined total of bulk sales costs and royalties is expected to be 26% of the Company's net product sales.

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### 13. NEW ACCOUNTING PRONOUNCEMENTS

In July 2001, the Financial Accounting Standards Board (FASB) issued SFAS No. 141, Business Combination, and SFAS No. 142, Goodwill and Other Intangible Assets. Statement No. 141 requires that all business combinations initiated after June 30, 2001 be accounted for using the purchase method of accounting. Statement No. 142 discusses how intangible assets that are acquired should be accounted for in financial statements upon their acquisition and also how goodwill and other intangible assets should be accounted for after they have been initially recognized in the financial statements. Beginning on January 1, 2002, with the adoption of Statement No. 142, goodwill and certain purchased intangibles existing on June 30, 2001, will no longer be subject to amortization over their estimated useful life. Rather the goodwill and certain purchased intangibles will be subject to an assessment for impairment based on fair value. The provisions of Statement No. 142 are required to be applied starting with the fiscal years beginning after December 15, 2001. The Company does not expect adoption of these statements to have a material impact on its financial position or results of operations.

In August 2001, the FASB issued SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. This statement supercedes FASB Statement No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of," and the accounting and reporting provisions of APB Opinion No. 30, "Reporting the Results of Operations - Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions." Under this statement it is required that one accounting model be used for long-lived assets to be disposed of by sale, whether previously held and used or newly acquired, and it broadens the presentation of discontinued operations to include more disposal transactions. The provisions of this statement are effective for financial statements issued for fiscal years beginning after December 15, 2001, and interim periods within those fiscal years, with early adoption permitted. The Company does not expect adoption of this statement to have a material impact on its financial position or results of operations.

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### MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

#### OVERVIEW

Genome Therapeutics Corp. ("we", "our", or "us") is a leader in the commercialization of genomics-based drug discovery. We have over ten years of experience in genomics research and have been one of the original recipients of funding from the United States government under its genome programs. Our commercial strategy is to use our genomics and related proprietary technologies to identify and validate novel drug targets for commercialization. Our two areas of scientific focus are the discovery and characterization of novel targets for human diseases and infectious diseases. We also commercialize our sequencing capabilities through our GenomeVision™ Services business, which we established in July 1999 to provide high quality, industrial scale sequencing to pharmaceutical and biotechnology companies on a fee for service basis. In May 1997, we introduced a non-exclusive genetic database, the PathoGenome™ Database, which provides subscribers with genetic information to identify gene targets. We believe that our genomic discoveries and information from our database will lead to the development of novel therapeutics, vaccines, and diagnostic products. To complement these established genomics programs, we expanded our drug discovery pipeline in October 2001 with the acquisition of Ramoplanin, a novel anti-infective in Phase III clinical trials for the prevention of bloodstream infections caused by vancomycin-resistant enterococci

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We receive payments from our strategic partners based on license fees, contract research and milestone payments during the term of the alliance. In addition, subscribers to our PathoGenome Database pay access fees for the information they obtain. Once a product resulting from a research alliance or a subscriber's use of the PathoGenome Database is commercialized, we are entitled to receive royalty payments based upon product revenues. 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 the strategic partners to conduct preclinical tests and clinical trials, obtain regulatory clearances, manufacture, sell, and distribute the product. Accordingly, we do not expect to receive royalties from these alliances for many years, if at all. Additionally, we sell, as a contract service business, high quality genomic sequencing information to third parties, including pharmaceutical companies, biotechnology companies, governmental agencies, and academic institutions.

Our primary sources of revenue are from alliance agreements with pharmaceutical company partners, subscription agreements to our PathoGenome Database and government research grants and contracts. Currently, we have seven strategic research 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 *H. pylori*. In August 1999, the sponsored 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. We entered into an alliance with Schering-Plough in December 1995. Under this alliance, Schering-Plough can use our *Staph. aureus* genomic database to identify new gene targets for the development of novel antibiotics. 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 September 1997, we established our third research alliance with Schering-Plough for the development of new pharmaceutical products to treat fungal infections. 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 December 1999, we entered into a strategic alliance with Wyeth-Ayerst to develop drugs based on our genetic research to treat osteoporosis.

In May 1997, we introduced our PathoGenome Database and sold our first subscription. Since that date, we have continued to contract with subscribers on a non-exclusive basis, and, as of September 29, 2001, we had a total of seven subscribers. Under our agreements, the subscribers receive non-exclusive access to information relating to microbial organisms in our PathoGenome

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Database. Subscriptions to the database generate revenue over the term of the subscription with the potential for royalty payments to us from future product sales.

Since 1989, the United States government has awarded us a number of research grants and contracts related to government genomics programs. The scope of the research covered by grants and contracts encompasses technology development, sequencing production, technology automation, and disease gene identification. These programs strengthen our genomics technology base and enhance the expertise of our scientific personnel. In July 1999, the government

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named us as one of the nationally funded DNA sequencing centers of the international Human Genome Project. We are participating in an international consortium in a full-scale effort to sequence the human genome. We will receive funding from the National Human Genome Research Institute (NHGRI) under the Human Genome Project of up to \$17.4 million over a forty-four month period, of which \$14.1 million is appropriated through February 2002. In October 1999, NHGRI appointed us as one of the initial centers in the Mouse Genome Sequencing Network. The NHGRI agreed to provide us with funding under this program of up to \$13.4 million over a three-year period, of which \$9.3 million is appropriated through November 2001. In August 2000, we were named as one of two primary centers for the Rat Sequencing Program by NHGRI. As part of the agreement, we switched our focus from the mouse genome to the rat genome and agreed to use all remaining funding under the mouse genome award and a portion of the remaining funding under the human genome award to participate in the rat genome initiative. These programs are subject to annual appropriations by the government based upon the availability of government funds and the achievement by us of certain milestones.

On October 8, 2001, subsequent to quarter-end, we acquired an exclusive license in the United States and Canada for a novel antibiotic, Ramoplanin, from Biosearch Italia S.p.A (Biosearch Italia). We will assume responsibility for the product development in the United States of Ramoplanin, currently in Phase III clinical trials. The agreement provides us with exclusive rights to develop and market oral Ramoplanin in the U.S. and Canada. Biosearch Italia will provide the bulk material for manufacture of the product and will retain all other rights to market and sell Ramoplanin. In addition to purchasing bulk material from Biosearch Italia, we will fund the completion of clinical trials, make payments upon achievements of specified milestones and pay a royalty to Biosearch Italia on product sales.

We have incurred significant operating losses since our inception. As of September 29, 2001, we had an accumulated deficit of approximately \$74 million. Our losses are primarily from costs associated with prior operating businesses and research and development expenses. These costs have often exceeded our revenues generated by our alliances, subscription agreements and government contracts and 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.

We are subject to risks common to companies in our industry including unproven technology and business strategy, reliance upon collaborative partners and others, rapid technological change, history of operating losses, need for future capital, competition, patent and proprietary rights, dependence on key personnel, uncertainty of regulatory approval, uncertainty of pharmaceutical pricing, healthcare reform and related matters, availability of, and competition for, unique family resources, and volatility of our stock.

### RESULTS OF OPERATIONS

THIRTEEN-WEEK PERIODS ENDED SEPTEMBER 23, 2000 AND SEPTEMBER 29, 2001

#### REVENUES

Contract research, licenses, milestones and subscription fees increased 25% from \$5,925,000 for the thirteen-week period ended September 23, 2000 to \$7,378,000 for the thirteen-week period ended September 29, 2001. The increase in contract research, licenses, milestones and subscription fees was primarily attributable to an increase in revenue recognized under our GenomeVision Services



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business, which provides sequencing services for the National Human Genome Research Institute as a participant in the International Human Genome Project and the Rat Genome Sequencing projects, as well as our biotechnology and pharmaceutical customers.

### COSTS AND EXPENSES

Total costs and expenses increased 51% from \$8,217,000 for the thirteen-week period ended September 23, 2000 to \$12,440,000 for the thirteen-week period ended September 29, 2001. Research and development expense, which includes internal research and development and research funded pursuant to arrangements with our strategic alliances, commercial sequencing customers and the U.S. government, increased 52% from \$6,505,000 in the thirteen-week period ended September 23, 2000 to \$9,881,000 for the thirteen-week period ended September 29, 2001. The increase was primarily due to an increase in costs and expenses associated with an expansion of our internal research programs, specifically in the area of infectious diseases and human gene discovery, as well as an increase in revenues derived from our GenomeVision Services business, as mentioned above. The increase consisted of an increase in payroll and related expenses, laboratory supplies and overhead expenses related to our operations.

Selling, general and administrative expenses increased 50% from \$1,711,000 for the thirteen-week period ended September 23, 2000 to \$2,559,000 for the thirteen-week period ended September 29, 2001 reflecting primarily an expansion in the areas of corporate development, sales and marketing and clinical development. The increase consisted of an increase in payroll and related expenses, as well as recruiting and consulting expenses.

### INTEREST INCOME AND EXPENSE

Interest income decreased 11% from \$1,180,000 for the thirteen-week period ended September 23, 2000 to \$1,056,000 for the same period ended September 29, 2001, reflecting primarily a lower interest earned on investments.

Interest expense decreased 18% from \$211,000 for thirteen-week period ended September 23, 2000 to \$174,000 for the same period ended September 29, 2001, due primarily to a decrease in outstanding balances under our long-term obligations.

### THIRTY-NINE WEEK PERIODS ENDED SEPTEMBER 23, 2000 AND SEPTEMBER 29, 2001

#### REVENUES

Contract research, licenses, milestones and subscription fees increased 41% from \$19,109,000 for the thirty-nine week period ended September 23, 2000 to \$26,858,000 for the thirty-nine week period ended September 29, 2001. The increase was primarily attributable to a \$5 million milestone payment received in June 2001 from our strategic partner, Wyeth-Ayerst, associated with the identification of a high bone mass gene under our osteoporosis program. The increase in contract research, licenses, milestones and subscription fees was also due to an increase in revenue recognized under our GenomeVision Services business, which provides sequencing services for the National Human Genome Research Institute as a participant in the International Human Genome Project and the Rat Genome Sequencing projects, as well as our biotechnology and pharmaceutical customers.

### COSTS AND EXPENSES

Total costs and expenses increased 32% from \$24,021,000 for the thirty-nine week period ended September 23, 2000 to \$31,638,000 for the thirty-nine week period ended September 29, 2001. Research and development expense, which

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includes internal research and development and research funded pursuant to arrangements with our strategic alliances, commercial sequencing customers and the U.S. government, increased by 31% from \$19,276,000 for the thirty-nine week period ended September 23, 2000 to \$25,254,000 for the thirty-nine week period ended September 29, 2001. The increase was primarily attributable to an expansion of our internal research programs, specifically in

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the area of infectious diseases and human gene discovery, as well as an increase in revenues derived from our GenomeVision Services business, as mentioned above. The increase consisted of an increase in payroll and related expenses, laboratory supplies and overhead expenses related to our operations.

Selling, general and administrative expenses increased 35% from \$4,746,000 for the thirty-nine week period ended September 23, 2000 to \$6,384,000 for the thirty-nine week period ended September 29, 2001 reflecting primarily an expansion in the areas of corporate development, sales and marketing and clinical development. The increase consisted of an increase in payroll and related expenses, as well as recruiting and consulting expenses.

### INTEREST INCOME AND EXPENSE

Interest income increased 52% from \$2,100,000 for the thirty-nine week period ended September 23, 2000 to \$3,186,000 for the same period ended September 29, 2001, reflecting primarily an increase in funds available for investment. The increase in funds available for investment was primarily due to proceeds received last year from the sale of common stock.

Interest expense decreased 11% from \$627,000 for the thirty-nine week period ended September 23, 2000 to \$556,000 for the same period ended September 29, 2001 due primarily to a decrease in outstanding balances under our long-term obligations.

### LIQUIDITY AND CAPITAL RESOURCES

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

As of September 29, 2001, we had cash, cash equivalents, restricted cash, and short-term and long-term marketable securities of approximately \$72,525,000. In July 2001, we sold 127,500 shares of common stock in a series of transactions through the NASDAQ National Market, resulting in net proceeds of \$1,672,000. In fiscal 2000, we sold 1,500,000 shares of common stock in a series of transactions through the NASDAQ National Market, resulting in net proceeds of \$44,723,000. During fiscal 2000, we issued 1,532,302 shares of common stock related to the exercise of stock options, resulting in net proceeds of approximately \$4,155,000. In fiscal 2000, we also sold 678,610 shares of common stock to bioMerieux, a strategic alliance partner, resulting in net proceeds of approximately \$3,732,000. For the thirty-nine week period ended September 29, 2001, we issued 342,893 shares of common stock related to the exercise of stock options and the employee stock purchase plan, resulting in proceeds received of \$1,188,000.

We have various arrangements under which we financed certain office and laboratory equipment and leasehold improvements. At September 29, 2001, we had an aggregate of \$6,505,000 outstanding under our borrowing arrangements, which are repayable over the next 36 months, of which \$3,917,000 is repayable within the next 12 months. Under these arrangements, we are required to maintain

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certain financial ratios, including minimum levels of tangible net worth, total indebtedness to tangible net worth, minimum cash level, debt service coverage and minimum restricted cash balances. As of September 29, 2001, the Company was in compliance with all of these covenants. The Company had no additional borrowing capacity under these capital lease agreements at September 29, 2001.

Our operating activities provided cash of \$1,335,000 for the thirty-nine week period ended September 29, 2001, primarily due to a decrease in interest receivable, accounts receivable and unbilled costs & fees, an increase in accounts payable, as well as noncash expenditures such as depreciation and amortization, stock-based compensation expense, and loss on disposal of fixed assets. Cash provided by operations for the thirty-nine week period ended September 29, 2001 was partially offset by our net loss, and an increase in prepaid expenses and other current assets, as well as a decrease in deferred revenue. Our operating activities provided cash of \$1,597,000 for the thirty-nine week period ended September 23, 2000, primarily due to a decrease in accounts receivable, unbilled costs & fees, an increase in accounts payable and accrued expenses, as well as noncash expenditures

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such as depreciation and amortization, stock-based compensation expense, and loss on disposal of fixed assets. Cash provided by operations for the thirty-nine week period ended September 23, 2000 was partially offset by our net loss, and a decrease in deferred revenue.

Our investing activities provided cash of \$16,109,000 for the thirty-nine week period ended September 29, 2001 from the conversion of marketable securities to cash and cash equivalents, partially offset by the purchase of marketable securities and property and equipment. Our investing activities used cash of \$14,586,000 for the thirty-nine week period ended September 23, 2000 from the purchase of marketable securities, partially offset by the conversion of marketable securities to cash and cash equivalents and net proceeds received under equipment finance arrangements.

Capital expenditures, including property and equipment acquired under capital leases, totaled \$3,395,000 for the thirty-nine week period ended September 29, 2001. Purchases consisted primarily of laboratory and computer equipment. We currently estimate that we will acquire an additional \$1,500,000 in capital property and equipment in fiscal 2001 consisting primarily of computer, laboratory equipment, and additions to leasehold improvement. We intend to finance the majority of capital purchases made during the fourth quarter of fiscal 2001 under new equipment financing arrangements, yet to be negotiated.

Our financing activities used cash of \$1,393,000 for the thirty-nine week period ended September 29, 2001, primarily for payments of long-term obligations, partially offset by proceeds received from the sale of equity securities, exercise of stock options, and the sale of common stock under the employee stock purchase plan. Our financing activities provided cash of approximately \$44,853,000 for the thirty-nine week period ended September 23, 2000, primarily from the sale of equity securities, exercise of stock options, sale of common stock under the employee stock purchase plan, net of payments of long-term obligations.

At August 31, 2000, we had net operating loss and tax credit (investment and research) carryforwards of \$87,055,000 and \$3,071,000, 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

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shareholders over a three-year period in excess of 50%. Additionally, certain of these losses are expiring due to the limitations of the carryforwards period.

We expect development expenditures associated with the acquisition of Ramoplanin to be approximately \$15-20 million through the end of 2002. We believe that under our current rate of investment in both clinical development and genomics research and development, our existing capital resources are adequate for the foreseeable future. There is no assurance, however, that changes in our plans or events affecting our operations will not result in accelerated or unexpected expenditures.

We may seek additional funding in the future through public or private financing. Additional financing may not be available when needed, or if available, it may not be on terms acceptable to us. To the extent that we raise additional capital by issuing equity or convertible debt securities, ownership dilution to stockholders will result.

We do not currently use derivative financial instruments. We generally place our marketable security investments in high quality credit instruments, as specified in our investment policy guidelines; the policy also limits the amount of credit exposure to any one issue, issuer, and type of instrument. We do not expect any material loss from our marketable security investments and therefore believe that our potential interest rate exposure is limited.

This Form 10-Q and documents we have filed with the Securities and Exchange Commission contain forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements represent our management's judgement regarding future events. Forward-looking statements typically are identified by use of terms such as "may," "will," "should," "plan," "expect," "intend," "anticipate," "estimate," and similar words, although some forward-looking statements are expressed differently. All forward-looking statements, other than statements of historical fact, included in this report regarding our financial

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position, business strategy and plans or objectives for future operations are forward-looking statements. We cannot guarantee the accuracy of the forward-looking statements, nor do we plan to update these forward-looking statements. You should be aware that our actual results could differ materially from those contained in the forward looking statements due to a number of risks affecting our business, including the ability of the Company and its alliance partners to (i) successfully develop products based on the Company's genomic information, (ii) obtain the necessary governmental approvals, (iii) effectively commercialize any products developed before its competitors and (iv) obtain and enforce intellectual property rights, as well as the risk factors set forth in the Exhibit 99 to the Company's Annual Report on Form 10-K for the year ended August 31, 2000 and those set forth in other filings that we may make with the Securities and Exchange Commission from time to time.

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### Part II

Item 1. Legal Proceedings  
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None

Item 2. Changes In Securities

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None

Item 3. Defaults Upon Senior Securities  
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None

Item 5. Other Information  
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None.

Item 6. Exhibits and Reports on Form 8-K  
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a) Exhibits:  
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3.1 By-laws of Genome Therapeutics Corp. (amended through July 24, 2001)

10.2 Employment letter with Steven M. Rauscher, dated June 15, 2001

10.3 Employment letter with Stephen Cohen, dated June 15, 2001

10.5 Employment letter with Richard Labaudinere, PhD, dated June 15, 2001

b) Reports on Form 8-K  
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Report on Form 8-K filed on July 2, 2001 to report the Company's engagement letter with Tucker Anthony Sutro to retain Tucker Anthony as our non-exclusive agent in connection with the sale of up to 1,950,000 registered shares of Genome Therapeutics Corp.

Report on Form 8-K filed on July 9, 2001 to report the Company's press release announcing the financial results for the third quarter of its fiscal 2001.

Report on Form 8-K filed on July 16, 2001 to report the Company's press release announcing the extension of its collaboration with Wyeth-Ayerst Laboratories.

Report on Form 8-K filed on August 9, 2001 to report that the Company's Board of Directors had approved a change in the Company's fiscal year from August 31 to December 31, as of fiscal year ended December 31, 2000.

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Signature

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has 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, SVP & CFO  
(Principal Financial Officer)

Date: November 13, 2001

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