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GENOME THERAPEUTICS CORP

Form 10-Q

January 09, 2001

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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 Quarter Ended: November 25, 2000

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 [X] 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

22,288,658

\$.10 PAR VALUE

Outstanding January 5, 2001

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Genome Therapeutics Corp. and Subsidiary

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GENOME THERAPEUTICS CORP. AND SUBSIDIARY CONSOLIDATED CONDENSED BALANCE SHEETS

	August 31, 2000	November 25, 2000 (Unaudited)
<hr style="border-top: 1px dashed black;"/>		
Assets		
Current Assets:		
Cash and cash equivalents	\$52,111,172	\$ 9,213,422
Marketable securities	22,348,841	51,207,530
Interest receivable	574,603	1,474,415
Accounts receivable	268,498	227,998
Unbilled costs and fees	548,807	280,410
Prepaid expenses and other current assets	383,929	832,528
Total current assets	76,235,850	63,236,303
Equipment and leasehold improvements, at cost:		
Laboratory and scientific equipment	18,465,674	18,986,789
Leasehold improvements	8,260,884	8,302,308
Office equipment and furniture	1,114,195	1,126,272
	27,840,753	28,415,369
Less accumulated depreciation and amortization	14,392,805	15,164,532
	13,447,948	13,250,837

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Restricted cash	200,000	200,000
Long-term marketable securities	1,224,184	12,475,937
Other assets	227,541	218,916
	-----	-----
Total assets	\$91,335,523	\$89,381,993
	=====	=====

Liabilities and Shareholders' Equity

Current Liabilities:		
Accounts payable	\$ 1,543,603	\$ 1,649,705
Accrued expenses	3,240,423	3,232,984
Deferred revenue	3,013,847	2,702,667
Current maturities of long-term obligations	4,719,604	4,588,012
	-----	-----
Total current liabilities	12,517,477	12,173,368
Long-term obligations, net of current maturities	4,543,201	3,732,887
Shareholders' equity	74,274,845	73,475,738
	-----	-----
Total liabilities and shareholders' equity	\$91,335,523	\$89,381,993
	=====	=====

See Notes to Condensed Consolidated Financial Statements.

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GENOME THERAPEUTICS CORP. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS

	Thirteen Weeks Ended	
	November 27, 1999	November 25, 2000
	(Unaudited)	
	-----	-----
Revenues:		
Contract research, licenses, and subscription fees	\$ 6,035,002	\$ 5,610,956
Costs and Expenses:		
Research and development	5,341,305	6,546,770
Selling, general and administrative	969,645	1,683,895
	-----	-----
Total costs and expenses	6,310,950	8,230,665
	-----	-----
Loss from Operations	\$ (275,948)	\$ (2,619,709)
	-----	-----
Interest income	363,671	1,229,985
Interest expense	(209,326)	(208,033)
	-----	-----
Net interest income	154,345	1,021,952
	-----	-----
Net loss	\$ (121,603)	\$ (1,597,757)
	=====	=====

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Net Loss per Common Share:		
Basic and diluted	\$ (0.01)	\$ (0.07)
	=====	=====
Weighted average common shares outstanding:		
Basic and diluted	18,947,684	22,279,734
	=====	=====

See Notes to Condensed Consolidated Financial Statements.

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GENOME THERAPEUTICS CORP. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS

		Thirteen We November 27, 1999 (Unaudi

Cash Flows from Operating Activities:		
Net loss		\$ (121,603)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization		960,624
Loss on disposal of fixed assets		--
Stock-based compensation		95,208
Changes in assets and liabilities:		
Interest receivable		(298,617)
Accounts receivable		(36,668)
Unbilled costs and fees		(56,775)
Prepaid expenses and other current assets		(389,111)
Accounts payable		1,469,089
Accrued expenses		247,264
Deferred revenue		2,004,009

Total adjustments		3,995,023

Net cash provided by (used in) operating activities		3,873,420

Cash Flows from Investing Activities:		
Purchases of marketable securities		(5,353,510)
Maturities of marketable securities		10,396,000
Purchases of equipment and leasehold improvements		(1,652,777)
Decrease in other assets		8,625

Net cash provided by (used in) investing activities		3,398,338

Cash Flows from Financing Activities:		
Proceeds from sale of common stock		98,877
Proceeds from exercise of stock options		3,732,115
Payments on long-term obligations		(813,426)

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Net cash provided by (used in) financing activities	3,017,566

Net Increase (Decrease) in Cash and Cash Equivalents	10,289,324
Cash and Cash Equivalents, at beginning of period	12,802,162

Cash and Cash Equivalents, at end of period	\$ 23,091,486
	=====
Supplemental Disclosure of Cash Flow Information:	
Interest paid during period	\$ 209,326
	=====
Income taxes paid during period	\$ 4,800
	=====
Supplemental Disclosure of Non-cash Investing and Financing Activities:	
Equipment acquired under capital lease obligations	\$ 372,000
	=====
Bonuses paid through grant of stock options	\$ --
	=====

See Notes to Condensed Consolidated Financial Statements.

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

1. BASIS OF PRESENTATION

The condensed consolidated 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 condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements and include all adjustments (consisting only of normal recurring accruals) 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 results of operations for the thirteen-week periods ended November 25, 2000 are not necessarily indicative of the results to be expected for the full fiscal year. The accompanying condensed consolidated 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.

2. REVENUE RECOGNITION

Revenues consist of license fees, contract research and subscription fees from the PathoGenome™ Database which were derived from alliances with pharmaceutical companies, government grants, and fees received from custom gene sequencing and analysis. 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. License fees are recognized as earned.

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Subscription fees from the PathoGenome Database are recognized ratably over the life of the subscription. Milestone payments 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 received prior to revenue recognition.

Staff Accounting Bulletin (SAB) No. 101, Revenue Recognition, was issued in December 1999 and is effective for companies with fiscal years beginning after December 15, 2000. SAB No. 101 will require companies to recognize certain up-front nonrefundable fees over the life of the related alliances when such fees are received in conjunction with alliances that have multiple elements. The Company is required to adopt this new accounting principles through a cumulative charge to its statement of operations, in accordance with Accounting Principles Board (APB) Opinion No. 20, Accounting Changes, no later than the fourth quarter of fiscal 2001. The Company believes that the adoption of SAB No. 101 will not have a material impact on its future operating results as it relates to the up-front nonrefundable payments and milestone payments received in connection with alliances.

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 and diluted earnings per share were determined by dividing net loss by the weighted average common 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 and directors' deferred stock that were not included in diluted net loss per common share were 3,211,051 and 3,385,715 at November 25, 2000 and November 27, 1999, respectively.

4. CASH, CASH EQUIVALENTS AND MARKETABLE SECURITIES

The Company applies SFAS No. 115, Accounting for Certain Investments in Debt and Equity Securities. At November 25, 2000 and August 31, 2000, the Company's cash equivalents and marketable securities are classified as held-to-maturity, as the Company has the positive intent and

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ability to hold these securities to maturity. Cash equivalents are short-term, highly liquid investments with original maturities of less than three months. 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 8 months at November 25, 2000.

At August 31, 2000 and November 25, 2000, the Company's cash, cash equivalents and marketable securities consisted of the following:

August 31, 2000	November 25, 2000

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Cash and Cash Equivalents:

Cash.....	\$ 42,211,172	\$ 8,363,422
Debt securities.....	9,900,000	850,000
	\$ 52,111,172	\$ 9,213,422

Marketable Securities:

Corporate and other debt securities.....	\$ 23,573,025	\$ 63,683,467
	\$ 23,573,025	\$ 63,683,467

The Company has \$200,000 in restricted cash in connection with certain long-term obligations (see Note 8).

5. 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.

6. 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 loss for the thirteen-week periods ended November 25, 2000 and November 27, 1999 were the same as reported net loss for those periods.

7. 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 substantially all assets are located in the United States.

8. LONG-TERM OBLIGATIONS

On February 23, 2000, the Company entered into an equipment lease line of

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credit under which it may finance up to \$4,000,000 of laboratory, computer and office equipment. The Company, at its discretion, can enter into either 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 November 25, 2000, the Company has entered into \$144,000 in operating leases and \$3,692,000 in capital leases. The interest rates under the capital leases range from 9.31% to 10.37%. The Company had approximately \$164,000 available under this line of credit at November 25, 2000.

The Company had entered into other capital lease line 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. We had no additional borrowing capacity under these capital lease agreements at November 25, 2000.

9. 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 approximately \$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 approximately \$13.5 million in license fees, expense allowances, milestone payments and research funding under the Astra agreement through November 25, 2000.

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 thirteen-week periods ended November 25, 2000 and November 27, 1999, the Company recorded \$0 and \$13,000, respectively, under this agreement, which consisted of contract research revenue.

(b) SCHERING-PLOUGH

In December 1995, the Company entered into a strategic alliance and license 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

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granted Schering-Plough exclusive access to the Company's proprietary Staph. aureus genomic sequence database. The Company also granted

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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.

Under this agreement, Schering-Plough agreed to pay an initial license fee and fund a research program for a minimum of two-and-a-half years with an option to extend. In June 2000, Schering-Plough elected to extend the research program for the second time through at least September 2001. Under the agreement as extended, 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 has also granted Schering-Plough a right of first negotiation if during the term of the research plan the Company desires to enter into an alliance with a third party with respect to the development or sale of any compounds that are targeted against, as their primary indication, the pathogen that is the principal subject of the Company's agreement with Schering-Plough. 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. Subject to certain limitations, the Company retained the rights to make, use and sell diagnostic products developed based on the Company's genomic database licensed to Schering-Plough or the technology developed in the course of the research program. A total of \$19.8 million has been received through November 25, 2000.

For the thirteen-week periods ended November 25, 2000 and November 27, 1999, the Company recorded revenue of \$411,000 and \$587,000, 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, (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 agreed to pay an initial license fee and an expense allowance to the Company. Schering-Plough was required to fund a research program for a minimum number of years with an option to extend. In July 1998, Schering-Plough amended the original agreement in order to accelerate the

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research effort being undertaken. In May 2000, Schering-Plough extended this research alliance through at least December 2001. In addition, upon completion of certain scientific developments, Schering-Plough will make milestone payments to the Company, as well as pay royalties to the Company based on 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, excluding royalties. Of the total potential payments, approximately \$31.4 million represents license fees and research payments, and \$44.5 million represents milestone payments based on achievement of research and product development milestones. A total of \$29.4 million has been received through November 25, 2000.

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For the thirteen-week period ended November 25, 2000 and November 27, 1999, the Company recorded revenue of \$1,101,000 and \$1,439,000, respectively, under this agreement, which consisted primarily of contract research revenue.

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. 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 in the course of the research program. In return, Schering-Plough agreed to fund a research program for a minimum number of years with an option to extend. In December 1999, Schering-Plough extended this alliance through September 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, approximately \$9.7 million represents sponsored research payments and \$23.0 million represents milestone payments based on achievement of research and product development milestones. A total of \$11.2 million has been received through November 25, 2000. 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 10).

For the thirteen-week period ended November 25, 2000, the Company recorded revenue of \$321,000 under this agreement, which consisted of contract research revenue. For the thirteen-week period ended November 27, 1999, the Company recorded revenue of \$1,654,000 under this agreement, which consisted of contract research revenue and a milestone payment.

(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 in 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 \$15.6 million over a three-year period, of which \$7.6 million is appropriated through October 2001. For the thirteen-week periods ended November 25, 2000 and November 27, 1999, the Company recorded revenue of approximately \$1,062,000 and \$912,000, respectively, in connection with this international Human Genome Project.

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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 \$12.9 million in funding over three years with respect to this agreement, of which \$5.2 million is appropriated through December 2000. 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 all remaining funding under the mouse award to commence this rat genome initiative. For the thirteen-week periods ended November 25, 2000 and November 27, 1999, the Company recorded revenue of approximately \$1,050,000 and \$51,000, respectively, under this agreement.

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. The government's failure to fund our research in this area not only would end the Company's participation in the program, but might adversely affect the industry-wide perception of genomics and the utility of genomic information.

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(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 10), 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. For the thirteen-week periods ended November 25, 2000 and November 27, 1999, the Company recorded revenue of \$297,000 and \$89,000, respectively, which consists of research funding and the amortization of the up-front license fees. A total of \$2.2 million has been received through November 25, 2000.

(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 calls 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 will fund 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 the Company, excluding royalties, would exceed \$118 million.

For the thirteen week period ended November 25, 2000, the Company recorded revenue of approximately \$375,000, which consists of research funding and the amortization of the up-front license fee. A total of \$2.0 million has been received through November 25, 2000.

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10. DATABASE SUBSCRIPTIONS

The Company has entered into a number of PathoGenome™ Database subscriptions. The database subscription provides 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 November 25, 2000 and November 27, 1999, the Company recorded revenue of \$750,000 and \$1,063,000, respectively, under these agreements.

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

OVERVIEW

Genome Therapeutics Corp. ("GTC", "we", or "our") 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 the GTC Sequencing Center, which we established in July 1999 to provide high quality, industrial scale sequencing to pharmaceutical and biotechnology companies on a contract 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.

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 based upon product revenues 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

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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. For the thirteen-week periods ended November 25, 2000 and November 27, 1999, revenue recognized under our strategic alliance agreements with Schering-Plough accounted for approximately 33% and 61%, respectively, of our total revenues.

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 November 25, 2000, 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 Database. Subscriptions to the database generate revenue over the term of the subscription with the

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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 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 \$15.6 million over a three-year period, of which \$7.6 million is appropriated through October 2001. 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 \$12.9 million over a three-year period, of which \$5.2 million is appropriated through December 2000. 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 award to commence 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.

We have incurred significant operating losses since our inception. As of

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November 25, 2000, we had an accumulated deficit of approximately \$71.1 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 NOVEMBER 27, 1999 AND NOVEMBER 25, 2000

REVENUES

Contract research, licenses, and subscription fees decreased 7% from \$6,035,000 for the thirteen-week period ended November 27, 1999 to \$5,611,000 for the thirteen-week period ended November 25, 2000. The decrease in contract research, licenses and subscription fees was primarily attributable to a decline in contract research funding under our existing alliance agreements, lower subscription fees to our PathoGenome Database, as well as a milestone payment earned last year under one of our research agreements with Schering-Plough. The decrease in contract research, licenses and subscription fees was partially offset by an increase in revenue recognized under our government collaborations with the National Human Genome Research Institute to participate in the International Human Genome Project and the Rat (Mouse) Genome Sequencing projects.

COSTS AND EXPENSES

Total costs and expenses increased 30% from \$6,311,000 for the thirteen-week period ended November 27, 1999 to \$8,231,000 for the thirteen-week period ended November 25, 2000. Research and development expense, which includes internal research and development and research funded pursuant to arrangements with our strategic alliances and the U.S. government, increased from \$5,341,305 in the thirteen-week period ended November 27, 1999 to \$6,547,000 for the thirteen-week

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period ended November 25, 2000. The increase was primarily due to an increase in costs and expenses associated with the increase in revenues earned under our government collaborations with the National Human Genome Research Institute. 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 74% from \$970,000 for the thirteen-week periods ended November 27, 1999 to \$1,684,000 for the thirteen-week periods ended November 25, 2000. This increase was primarily attributable to an increase in payroll and related expenses, hiring and employee relocation expense. In addition, we recorded a charge for severance expenses in accordance with the terms of our severance agreement with Dr. Richard Gill.

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INTEREST INCOME AND EXPENSE

Interest income increased 238% from \$364,000 for the thirteen-week period ended November 27, 1999 to \$1,230,000 for the same period ended November 25, 2000, reflecting an increase in funds available for investment.

Interest expense decreased slightly from \$209,000 for the thirteen-week period ended November 27, 1999 to \$208,000 for the same period ended November 25, 2000.

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 sale of equity securities.

As of November 25, 2000, we had cash, cash equivalents, restricted cash and short-term and long-term marketable securities of approximately \$73,097,000. In fiscal 2000, we sold 1,500,000 shares of common stock in a series of transactions through the Nasdaq National Market, resulting in proceeds received of approximately \$44,723,000, net of issuance costs. During fiscal 2000, we issued 1,532,302 shares of common stock related to the exercise of stock options, resulting in proceeds received 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 proceeds received of approximately \$3,732,000, net of issuance costs.

We have various arrangements under which we financed certain office and laboratory equipment and leasehold improvements. At November 25, 2000, we had an aggregate of approximately \$8,321,000 outstanding under our borrowing arrangements which is repayable over the next 36 months, of which \$4,588,000 is repayable within the next 12 months. Under these arrangements, we are required to maintain 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. At November 25, 2000, we had approximately \$164,000 available under one of these arrangements for future borrowings.

Our operating activities used cash of approximately \$955,000 for the thirteen-week period ended November 25, 2000, primarily due to an our net loss, and increases in interest receivable, prepaid expense and other current assets, as well as a decrease in deferred revenue. Cash used in operations for the thirteen-week period ended November 25, 2000 was partially offset by noncash items such as depreciation and amortization, stock-based compensation, loss on sale on disposal of fixed assets, as well as an increase in accounts payable, and a decrease in unbilled costs and fees. For the thirteen-week period ended November 27, 1999 operating activities provided cash of approximately \$3,873,000 primarily due to increases in deferred revenue, accounts payable, accrued expenses, as well as depreciation and amortization, and amortization of stock-based compensation.

Our investing activities used cash of approximately \$40,795,000 for the thirteen-week period ended November 25, 2000 to purchase marketable securities, capital equipment and leasehold improvements, partially offset by the conversion of marketable securities to cash and cash equivalents. Our investing activities provided cash of approximately \$3,398,000 from the conversion of marketable

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securities to cash and cash equivalents, partially offset by the purchase of marketable securities and capital equipment and leasehold improvements.

Capital expenditures, including property and equipment acquired under capital leases, totaled \$989,000 for the thirteen-week period ended November 25, 2000. Purchases consisted primarily of laboratory and computer equipment. We currently estimate that we will acquire an additional \$4,000,000 in capital 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 fiscal 2001 under existing and new equipment financing arrangements, yet to be negotiated. We are in discussions with several potential sources of equipment financing.

Our financing activities used cash of approximately \$1,148,000 for the thirteen-week period ended November 25, 2000, primarily for payments of long-term obligations. Our financing activities provided cash of approximately \$3,018,000 for the thirteen-week period ended November 27, 1999, primarily from the sale of equity securities, exercise of stock options, net of payments of long-term obligations.

At August 31, 2000, we had net operating loss and tax credits (investment and research) carryforwards of approximately \$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 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 believe that under our current rate of investment in 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.

In June 1998, the Financial Accounting Standards Board (FASB) issued SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities. This statement establishes accounting and reporting standards for derivative instruments, including derivative instruments embedded in other contracts and for hedging activities. SFAS No. 133, as amended by SFAS No. 137, is effective for all fiscal quarters of fiscal years beginning after June 15, 2000. The adoption of SFAS No. 133 to have a material impact on its financial statements.

SAB No. 101 was issued in December 1999 and is effective for companies with fiscal years beginning after December 15, 2000. SAB No. 101 will require companies to recognize certain up-front nonrefundable fees over the life of the related alliances when such fees are received in conjunction with alliances that have multiple elements. The Company is required to adopt this new accounting

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principles through a cumulative charge to its statement of operations, in accordance with APB Opinion No. 20 no later than the fourth quarter of fiscal 2001. The Company believes that the adoption of SAB No. 101 will not have a material impact on its future operating results as it relates to the up-front nonrefundable payments and milestone payments received in connection with alliances.

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

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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 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

On November 22, 2000, the Company was named as a defendant, along with The Gel Company and PE Corporation, in a law suit brought by Commonwealth Biotechnologies, Inc. ("Commonwealth") in the United States District Court for the Eastern District of Virginia. The suit alleges infringement of a certain patent (Patent No. 6,110,683, Automated DNA Sequencer Loading Dye Which Contains a Lane Tracking Aid) issued to Commonwealth, misappropriation of trade secrets under the Virginia Uniform Trade Secrets Act, and unfair competition under the Lanham Act. The suit seeks, among other things, to enjoin the Company from infringing on the patent and from engaging in unfair competition, to obtain unspecified amounts of monetary damages and to obtain reimbursement of legal fees. The Company is vigorously defending against this suit and does not expect that the suit will have a material adverse impact on the Company's financial condition or results of operations. The Company cannot be certain, however, that it will prevail in the suit or that the outcome of the suit will not negatively affect the Company.

Item 2. CHANGES IN SECURITIES

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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:

10.1 Compound Discovery Collaboration Agreement dated as of October 17, 2000 between ArQule, Inc. and Genome Therapeutics Corp.*

* Certain Confidential material contained in the document has been omitted and filed separately with the SEC pursuant to Rule 24b-2 of the Securities Exchange Act of 1934.

b) Reports on Form 8-K

None.

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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/ Philip V. Holberton

Philip V. Holberton
(Principal Financial Officer)

Date: January 8, 2001

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