

GENOME THERAPEUTICS CORP
Form 10-K405
April 01, 2002

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SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

(MARK ONE)

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

For the fiscal year ended: December 31, 2001

or

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

Commission file number: 0-10824

Genome Therapeutics Corp.
(Exact name of registrant as specified in its charter)

Massachusetts
(State or other jurisdiction
of incorporation or organization)

04-2297484
(IRS employer
identification number)

100 Beaver Street, Waltham, Massachusetts
(Address of principal executive offices)

02453
(Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act: NONE

Securities registered pursuant to Section 12(g) of the Act:
COMMON STOCK, \$.10 PAR VALUE
(Title of Class)

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item
405 of Regulation S-K is not contained herein, and will not be contained, to the
best of registrant's knowledge, in definitive proxy or information statements
incorporated by reference in Part III of this Form 10-K or any amendment to this
Form 10-K

The aggregate market value of the voting stock held by non-affiliates of the
registrant as of March 27, 2002 was approximately \$131,327,000.

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The number of shares outstanding of the registrant's common stock as of March 27, 2002 was 22,831,030.

Documents Incorporated By Reference

Portions of the registrant's proxy statement for use at its Annual Meeting to be held on June 25, 2002 are incorporated by reference into Part III.

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PART I

ITEM 1. Business

Overview

We are a biopharmaceutical company focused on the discovery and development of pharmaceutical and diagnostic products. We have eight established product development programs. Our lead product candidate, Ramoplanin, is in Phase III clinical trials for the prevention of bloodstream infections caused by vancomycin-resistant enterococci (VRE). We have six alliances with pharmaceutical companies including Schering-Plough, AstraZeneca, Wyeth-Ayerst and bioMerieux, and a joint venture with ArQule. In addition to these eight projects, we have a portfolio of earlier stage internal drug discovery programs. We also maintain an active service business, GenomeVision™ Services, providing drug discovery services to pharmaceutical and biotechnology companies and to the National Human Genome Research Institute.

BioPharmaceutical Product Discovery and Development

We concentrate our product discovery and development efforts in two principal areas: (i) infectious diseases caused by bacterial and fungal pathogens and (ii) human diseases believed to have a significant genetic component. In both of these fields we have built integrated discovery platforms to discover genes and characterize their function. We use these platforms to pursue the discovery of new products through strategic alliances with corporate partners and through internal research programs.

We have long been a leader in the use of genomics to discover new drugs for the treatment of bacterial and fungal infections. In October 2001, we in-licensed the compound, Ramoplanin, and are developing it for the prevention of bloodstream infections caused by vancomycin-resistant enterococci (VRE). We have two ongoing discovery and development collaborations with Schering-Plough. The first is focused on new treatments for drug resistant bacterial infections, including Staph. aureus, and the second is focused on novel anti-fungals. We have partnered with AstraZeneca to develop treatments for ulcers caused by H. pylori and with bioM[erieux] to develop diagnostics for bacterial infections. We have formed a joint venture with ArQule, Inc. to discover and develop new broad-spectrum antibiotics. In addition to these collaborations, we have continued to invest in internal research programs in bacterial and fungal infections.

In addition to drug discovery for bacterial and fungal infections, we are leaders in the use of population genetics as a tool in discovering new therapies for the treatment of chronic human diseases. We have formed an alliance with Schering-Plough to discover new treatments for asthma and an alliance with Wyeth-Ayerst for the treatment of osteoporosis. We also continue to invest in the development of new therapies for the treatment of osteoporosis as well as neurological and psychiatric diseases.

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Scientific Background

Infectious Disease

The identification and characterization of the genes essential to the survival of a pathogen may lead to the development of innovative drugs to combat infection. We have sequenced the genomes of over 20 important pathogens and have developed a database that includes proprietary and publicly available genetic information from over thirty microbial organisms, including organisms responsible for the most prevalent bacterial infections. Our researchers have used this database to conduct cross-genome comparisons and identify genes conserved in a large number of pathogens. Then, through a series of technologies, we refer to as the PathoEssential™ platform, we have been able to identify conserved genes that are essential for survival of the organisms, (known as essential targets). Screening assays are then developed to screen compounds for activity against these conserved essential targets. In addition, we have developed a suite of technologies that allow us to characterize, profile, determine and/or confirm mechanism of action of compounds identified in our primary high-throughput screening assays.

We have built a high-throughput screening capability. In 2001, our first full year of operation, we generated over 2.2 million data points. We use biochemical and cell-based assays internally. We also collaborate with a third party, Cetek, to conduct affinity-based screening on targets of unknown function. To capitalize on this screening capability, we have built a diverse compound library from commercial sources of approximately 80,000 compounds selected based on chemical diversity and other "drug-like" properties. We have invested in our in vivo, pre-clinical capabilities and have commenced in vivo testing on several compounds.

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Chronic Human Diseases

A variety of factors cause human disease, including genetic defects, pathogens and environmental factors, with many of the most common life threatening and chronic diseases believed to have a genetic component. Consequently, the identification and characterization of genes associated with these chronic diseases may lead to new therapies and diagnostic tests.

The completion of the first draft of the human genome and additional genomics initiatives such as the SNP consortium have resulted in the generation of tremendous amounts of gene sequence and polymorphism information, but new products based on this information are yet to be discovered. Identifying genes that cause or are associated with a specific disease and determining how those genes contribute to the disease is a formidable challenge. Therefore, industrialized discovery technologies that can convert this large amount of genomic data into actual drug candidates are critical to translate these early-stage discoveries into actual treatments for human disease.

We have developed an integrated suite of technologies, tools and data management and analysis capabilities to bridge this gap between genomics data and drug candidates. We have developed sophisticated techniques for evaluating population resources to identify genes associated with chronic disease or rare genetic disorders. Our scientists carefully characterize human phenotypes and develop linkage maps to discover genes associated with human disease. We have designed an integrated platform of highly automated, industrial scale technologies that permits us to rapidly analyze and draw conclusions from genomic information. We believe our approach will allow our collaborators and us

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to effectively use genomic information to identify and validate targets that can be successfully developed into novel therapeutics and diagnostic products.

Our Drug Discovery and Development Strategy

Our strategy is to focus our drug discovery and development efforts on bacterial and fungal infections and chronic human diseases. We employ three pathways to discover and develop new products. Each path has a different level of internal vs external funding and different economics. The table below sets forth the typical funding and economic structure for the various pathways:

Pathway	Funding	GENE Economics
Drug Discovery Alliances	100% funded by alliance partner	<ul style="list-style-type: none"> . License fees . Milestone payments . Sponsored research . Royalties
Joint Ventures	50-50 shared funding	50-50 profit split
Internal Discovery Programs & In-Licensed Products	100% funded by GENE	100% to GENE, net of 3rd party royalties

Drug Discovery Alliances

We seek to form strategic alliances with major pharmaceutical companies to maximize the probability of success in drug discovery and development. This is particularly important for research programs that require the discovery and/or development capabilities of a major pharmaceutical company to fully exploit or that address market opportunities that would require a large, global sales and marketing infrastructure. In these alliances, typically, the alliance partner funds research efforts with us to discover genes, determine their function and develop assays to test compounds against those genes. As we successfully complete our portion of the program, the partner assumes responsibility for downstream drug discovery and development. We believe, for example, that our current alliances with Wyeth-Ayerst, Schering-Plough, AstraZeneca, and bioMerieux, all industry leaders in their fields, are providing us with the best opportunity to capitalize on our early genomics discoveries. We continue to meet or exceed our development schedule with all of our alliance partners and seek to extend or expand these alliances, when it is strategically beneficial to both parties.

We will continue to seek additional alliances, particularly in chronic human diseases. We believe that these diseases represent large commercial opportunities that require the resources of a major pharmaceutical company. We will seek partners that have franchises in the treatment of these major disease indications. We believe companies that have major research efforts and/or commercial products focused on a particular disease will continue to be motivated to utilize genomic information to develop novel products that will allow them to maintain or enhance their market leadership position.

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Joint Ventures

In late 2000, we made the strategic decision to begin investing more heavily in joint ventures and internally funded programs in infectious disease. Our goal is to invest in a number of these ventures to take advantage of development synergies that certain strategic partners can offer. This should allow us to accelerate the process of drug discovery as well as capture a larger share of the program value. Our joint venture with ArQule is an example of this kind of program. This venture is funded equally by both companies and is focused on discovering new broad-spectrum anti-bacterials. It combines our gene targets, assay development, screening and anti-bacterial discovery technologies with the extensive compound libraries and medicinal chemistry capabilities of our partner.

Internal Discovery Programs

We continue to invest to expand our internal drug discovery capabilities in bacterial and fungal infections. During the last two years, we have built a high-throughput screening capability. In 2001, our first full year of operation, we generated over 2.2 million data points. We have built a diverse compound library of approximately 80,000 compounds derived from commercial sources. We have invested in our in vivo, pre-clinical capabilities and have commenced in vivo testing on several compounds. While we will seek to partner some of these programs with larger companies, we will also seek to develop and commercialize some of these discoveries ourselves for niche opportunities, such as hospital-acquired infections or infections in immuno-compromised patients.

We continue to evaluate and invest in acquiring additional family resources (families whose members suffer from diseases with a significant inherited component) for new drug discovery programs in chronic human diseases. Additionally, we continue to invest in our platform to rapidly discover and characterize the function of genes associated with human disease. We plan to partner these programs with major pharmaceutical companies for downstream discovery, clinical development and commercialization.

In-licensed compounds for Clinical and Commercial Development

We seek to supplement our drug discovery efforts with an active in-licensing program. We seek to in-license products in pre-clinical and/or clinical development that will complement our internal drug discovery efforts for infectious diseases. Our first such product candidate, Ramoplanin, is in Phase III clinical trials for the prevention of bloodstream infections caused by VRE. We will also explore additional indications for this product candidate, potentially expanding and extending its value.

BioPharmaceutical and Diagnostic Programs

We have eight ongoing product development programs. Our lead product candidate, Ramoplanin, is in Phase III clinical trials for the prevention of bloodstream infections caused by VRE. We have six alliances with pharmaceutical companies including Schering-Plough, AstraZeneca, Wyeth-Ayerst and bioMerieux, and a joint venture with ArQule. In addition to these eight programs, we have a portfolio of earlier stage internal drug discovery programs.

Ramoplanin

Bacteria are commonly classified into two categories: gram-positive and gram-negative. Enterococci are a family of gram-positive bacteria that are part of the normal flora of the gastrointestinal tract. While these organisms do not normally cause infections in healthy people, they become a threat in patients that have a compromised immune system and are frequently found in hospitalized

patients. Enterococci are now the second most common cause of bloodstream infections acquired in the Intensive Care Units (ICUs) of hospitals in the United States. Enterococcal bloodstream infections in the ICU have been associated with a crude mortality of over 30%.

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For thirty years, the antibiotic of last resort for enterococcal bloodstream infections was vancomycin. However, the widespread use of vancomycin and other antibiotics such as third generation cephalosporins has increased the prevalence of resistant strains of enterococci, known as vancomycin-resistant enterococci (VRE). In 1999, more than 25% of intensive care unit enterococci infections were caused by VRE, a 47% increase from 1994.

Given its rapid spread and the difficulty in treating blood-borne infections, VRE has received significant attention from both the medical and public health communities. Most VRE is not only resistant to vancomycin, but also to other common antibiotics. This provides VRE with a selective advantage over other enterococcal isolates in the gut and enables resistant pathogens to easily colonize the human gastrointestinal (GI) tract. The morbidity and mortality associated with VRE bloodstream infections is substantially higher than for enterococcal bloodstream infections caused by vancomycin-sensitive strains of enterococci.

Given the high morbidity, mortality and cost of VRE bloodstream infections and the limited treatment options for active infections, a great deal of focus within the infectious disease community has been placed on infection control practices within the hospital to prevent VRE infections. Infection control has focused on screening to identify colonized patients and the use of barrier methods to avoid the spread of colonization to other patients. Typically, these require isolation of the patient in a room with negative air pressure and the "gowning and gloving" of physicians and nursing staff. Such patients are often not allowed to have family visitors.

The large quantity of VRE in the gut has motivated investigators to seek to de-colonize the gut in an attempt to prevent VRE bloodstream infections. However, attempts to prevent VRE bloodstream infections have been unsuccessful in the past. Bacitracin has been tried in combination with or without gentamicin or a tetracycline. Novobiocin has also been tried. It is believed that these approaches have not been successful due to lack of potency or the inability of the antibacterials to reach high enough levels in the gut to suppress VRE effectively.

In October 2001, we in-licensed Ramoplanin, a product under development as a novel antibiotic for the prevention of bloodstream infections caused by VRE, from Biosearch Italia S.p.A (Biosearch). Ramoplanin is a novel glycolipodepsipeptide antibiotic produced by fermentation of *Actinoplanes* species, with activity against gram-positive aerobic and anaerobic microorganisms. In preclinical studies Ramoplanin has been shown to be bactericidal for most gram-positive species, including methicillin-resistant staphylococci and VRE. Ramoplanin inhibits the bacterial cell wall peptidoglycan biosynthesis with a mechanism different from that of vancomycin, teicoplanin or other cell wall-synthesis inhibitors. No evidence of cross-resistance between Ramoplanin and other glycopeptide antibiotics has been observed. Ramoplanin has a unique profile (see Table 5) that may make it a particularly attractive compound for killing bacteria in the gastrointestinal tract. This may make the product a useful drug in the treatment of certain infections (*C. Difficile*) that occur in the GI tract. It may also make the compound effective in the prevention of bloodstream infections by gram positive organisms that are concentrated in the GI tract, including VRE.

Table 5: Ramoplanin Profile

Characteristic	Potential Advantage
Novel class of antibiotic	<ul style="list-style-type: none"> . No demonstrated cross-resistance with other antibiotics. . No demonstrated resistance
Orally administered, but not absorbed into bloodstream	<ul style="list-style-type: none"> . Concentrates and exerts its killing effects in the GI tract
Bactericidal	<ul style="list-style-type: none"> . Rapid killing effect. . Less likely to develop resistance
Gram Positive Spectrum	<ul style="list-style-type: none"> . Low potency against gram negative anaerobes. . Less likely to result in overgrowth of other opportunistic organisms. . Potential value vs C. Difficile

In a Phase II, multicenter, double-blind, placebo-controlled trial, oral Ramoplanin was well tolerated. In addition, after seven days of treatment, 90% of patients who were colonized with VRE at the beginning of the study had no detectable VRE in their gastrointestinal tract, while all of the placebo patients had detectable VRE (p<0.01). Ramoplanin has been granted Fast Track status

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by the FDA and is currently being tested in a Phase III clinical study. The ongoing Phase III study is designed to demonstrate whether oral prophylaxis with Ramoplanin reduces the incidence of VRE bloodstream infections in cancer patients known to carry VRE bacteria in their intestines. More than one-third of the planned 950 patients have been enrolled in the study at more than 40 clinical trial sites in the U.S. We expect to file a New Drug Application for Ramoplanin in 2004.

The license agreement provides us with exclusive rights to develop and market oral Ramoplanin in the U.S. and Canada. Biosearch will provide the bulk material for the manufacture of the product. Under the terms of the agreement, we paid Biosearch an initial consideration of \$2 million. Thereafter, we will make milestone payments of up to an additional \$8 million in a combination of cash and notes convertible into our stock if certain development milestones are met. In addition to purchasing bulk material from Biosearch, we will fund the completion of clinical trials and pay a royalty on product sales. The combined total of bulk product purchases and royalties is expected to be 26% of our net product sales.

The Company and Biosearch have established a joint committee to coordinate global efforts for the ongoing clinical development and future commercialization of Ramoplanin.

Drug Discovery Alliances

We form strategic alliances with major pharmaceutical companies to maximize

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our success in product discovery and development. The following table summarizes our existing product discovery and development partnerships:

Bacterial and Fungal Infections Alliances

Alliance Focus	Partner (Date of Agreement)	Status of Alliance	Proceeds Received of December 31, 2
Ulcers	AstraZeneca (September 1995)	Contract research program completed; Program transferred to AstraZeneca; Currently in lead optimization.	\$13.5 million
Drug Resistant Bacterial Infections	Schering-Plough (December 1995)	Contract research program substantively completed; Validated targets and screening assays transferred to Schering-Plough; Currently in high-throughput screening.	\$21.4 million
Fungal Infections	Schering-Plough (September 1997)	Contract research program substantively completed; Validated targets and screening assays transferred to Schering-Plough; Currently in high-throughput screening.	\$12.2 million
Infectious Disease Diagnostics	BioMerieux (September 1999)	PathoGenome Database delivered; identification of gene markers ongoing.	\$3.4 million

Human Disease Alliances

Alliance Focus	Partner (Date of Agreement)	Status of Alliance	Proceeds Received of December 31, 2
Osteoporosis	Wyeth-Ayerst Division of American Home Products (December 1999)	Identified specific gene mutation that leads to increased bone mass; Contract research extended through December 2002. Currently in high-throughput screening	\$8.1 million
Asthma	Schering-Plough (December 1996)	Two genes discovered. Identification of candidate genes ongoing; Contract research program extended to December 2002; Currently in high throughput	\$38.5 million

screening

* Assumes receipt or payment of all license fees, funded research and contingent payments for achieving milestones, after extensions

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and/or reallocations; excludes potential royalties

Bacterial and Fungal Infection Alliances

Ulcers

H. pylori infection affects an estimated 30% of the United States population, causing more than 5 million cases of peptic ulcer disease per year. Industry sources estimate that the market for ulcer disease products worldwide to be \$14.5 billion in 2001. The pathogen, H. pylori, is believed to be responsible for 90% of duodenal ulcers, the most common type of ulcer, and approximately 80% of gastric peptic ulcers. The World Health Organization has estimated that H. pylori is responsible for 550,000 new cases of stomach cancer per year worldwide. Using our sequencing technology, we completed the random sequencing and finishing of the genome of H. pylori. We believe that drugs targeted at genes essential to the survival of H. pylori will provide novel treatments for peptic ulcers.

In September 1995, we formed an alliance with AstraZeneca to identify genes critical to the survival of H. pylori and proteins on the surface of the bacterium that we believe to be likely targets for drugs. AstraZeneca is a leader in the field of products to treat peptic ulcer disease. Its anti-ulcer drug, Prilosec(R) was the world's biggest selling prescription drug in 2000 with sales of \$6.2 billion. As of December 31, 2001, we had received payments of \$13.5 million under this alliance and have rights to receive, based on attainment of milestones, an additional \$9.8 million of payments in addition to potential royalties. In August 1999, we had completed our research obligations under this alliance and had turned over validated drug targets and assays to AstraZeneca for pre-clinical testing. AstraZeneca recently announced that it had begun a lead optimization program on a lead identified through the high-throughput screening program conducted using one of these targets.

Drug Resistant Bacterial Infections

Infectious diseases remain the world's leading cause of premature death. Each year approximately 2 million patients in the U.S. develop antibiotic resistant infections while being treated in hospitals. Antibiotic resistant organisms, many of which have multiple antibiotic resistances, cause these infections. Industry sources estimate that the pharmaceutical market for antibiotic products worldwide was more than \$20 billion in 2000.

The pathogen Staph. Aureus is a common cause of skin, wound and blood infections. Staph. aureus infections are typically treated with antibiotics. In recent decades, the incidence of Staph. aureus infections that are resistant to available antibiotic treatments has risen. Using our high-throughput sequencing capabilities, we have sequenced the genome of antibiotic-resistant Staph. aureus. We believe that drugs targeted at genes essential to the survival of Staph. aureus will provide novel treatments for skin, wound and blood infections

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contracted in hospitals.

In December 1995, we formed an alliance with Schering-Plough to identify and validate gene targets for the development of drugs to treat Staph. aureus and other pathogens that have become resistant to current antibiotics. Schering-Plough is an established participant in the anti-infective market, and a leader in the utilization of genomics to discover novel anti-infective products. As of December 31, 2001, we had received payments of \$21.4 million under this alliance and have rights to receive, based on attainment of milestones, an additional \$24 million of payments as well as potential royalties. As of December 31, 2001, we had substantively completed our research obligations under this alliance and had turned over validated drug targets and assays to Schering-Plough for high-throughput screening.

Fungal infections

The past twenty years have seen dramatic changes in the pattern of fungal infections in humans. These pathogens have assumed a much greater importance because of their increasing incidence in immunocompromised patients, such as AIDS patients, transplant recipients, cancer patients and other groups of immunocompromised individuals. Increased international travel and misuse of antimicrobial agents have also contributed to this trend and the emerging resistance to certain treatments. Industry sources estimate that the global market for prescription antifungal drugs was approximately \$4.8 billion in 1999, with non-prescription fungal treatments adding significantly to overall market size. Currently, there are a limited number of antifungals available for use against hospital related fungal infections, and many of the products currently on the market have serious side effects. We believe that drugs targeted at genes that are essential to the survival of fungal pathogens will provide novel and effective treatments for fungal infections.

In September 1997, we formed an alliance with Schering-Plough to use our high-throughput sequencing capabilities and genomic

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tools to identify new, validated fungal targets for the development of drugs to treat fungal infections. Schering-Plough is a leader in the field of drugs targeted against fungal infections, with market leading products such as the Lotrimin AF(R) and Tinactin(R) lines of topical antifungals. As of December 31, 2001, we had received payments of \$12.2 million under this alliance and have rights to receive, based on attainment of milestones, an additional \$21.0 million of payments in addition to potential royalties. As of December 31, 2001, we had substantively completed our research obligations under this alliance and had turned over validated drug targets and assays to Schering-Plough for high-throughput screening.

Infectious disease diagnostics

The World Health Organization estimates that more than 13 million people die of an infectious disease worldwide each year, with many of those infections acquired in hospitals. There has been a global resurgence of infectious diseases, including the identification of new pathogens, the re-emergence of old infectious agents and the rapid spread of resistance to anti-infective agents. The ability to rapidly identify the specific microorganisms involved in disease is becoming increasingly important and complex, providing challenges and opportunities for infectious disease testing. Highly sophisticated and versatile methods are needed to identify a larger and more diverse list of pathogens, including variants with drug resistant characteristics. It is anticipated that nucleic acid tests incorporating such methods will be part of the fastest

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growing segment of the \$20 billion in vitro diagnostic global market.

In September 1999, we entered into a strategic alliance with bioMerieux to develop, manufacture and sell in vitro pathogen diagnostics for human clinical and industrial applications. A privately held company based in France, bioMerieux is one of the top 10 diagnostics companies in the world and the leader in the field of microbiology. The total amount of research and development funding approximates \$5.2 million for the four-year term of this agreement. As of December 31, 2001, we had received payments of \$3.4 million and have rights to receive future milestone payments and royalties based upon successful commercialization of diagnostic products.

Chronic Human Disease Alliances

Osteoporosis

Osteoporosis is a major health problem characterized by low bone mass that affects more than 200 million people worldwide and approximately one-third of post-menopausal women. In the U.S. alone, osteoporosis contributes to more than 1.5 million bone fractures per year. Estimated direct expenditures in the United States for osteoporosis and associated fractures are \$13.8 billion. Twin and family studies suggest a strong genetic component to the disease. Under a collaboration with Creighton University of Omaha, Nebraska, we have gained access to data from related individuals identified by Creighton who exhibit high bone mass. We believe the identification of genes regulating bone density and disease progression will lead to the discovery of novel drugs for treating osteoporosis by increasing bone mass, as well as the development of diagnostic tests.

In December 1999, we formed an alliance with Wyeth-Ayerst to develop drugs to treat osteoporosis based on our genetic research. Wyeth-Ayerst is a leader in the field of women's health with a broad array of products, including Premarin(R), a leading estrogen replacement therapy. As of December 31, 2001, we had received payments of \$8.1 million under this alliance and have rights to receive, subject to the achievement of milestones, up to a total of \$118.0 million in license fees, milestone payments and research support, as well as royalties on sales of any products developed. Under this alliance, we are carrying out functional studies to confirm the identity of target genes. During 2001, the research phase of this alliance was extended through December 31, 2002. This program has recently entered high-throughput screening.

Asthma

Asthma affects over 155 million people worldwide according to the World Health Organization and the incidence appears to be rising dramatically. In the United States, the incidence has doubled over the past two decades and affects approximately 4% to 10% of the United States population. The annual care associated with the disease exceeds \$15.0 billion in direct and indirect costs. Published research suggests that multiple genetic factors as well as environmental influences play a role in the disease. We believe that the asthma genes that we have identified will facilitate the development of superior diagnostics and novel drugs.

In December 1996, we formed an alliance with Schering-Plough to use our disease gene identification strategies to identify genes involved in the development of asthma. Schering-Plough has extended our alliance through December 2002. Schering-Plough is a leader in the field of allergy and respiratory care products, with products such as Afrin(R) nasal spray, the leading product in the

branded nasal spray market, and the Claritin(R) line of antihistamines, which generated \$3.1 billion of sales in 2000. As of December 31, 2001, we had received payments of \$38.5 million under this alliance and have rights to receive, based on attainment of milestones an additional \$42.5 million of payments as well as potential royalties. During 2001, we used our proprietary genomics tools, bioinformatics and high-throughput sequencing to discover two genes associated with asthma. These genes have been transferred to Schering-Plough for further drug discovery efforts. This program has advanced into high-throughput screening.

Arqule Joint Venture

In October, 2000, we formed a new joint venture with ArQule, Inc. The joint venture, which replaced an earlier 1998 collaboration agreement, includes a significantly increased commitment of shared, dedicated scientific and technical resources from both companies and includes joint ownership rights to all lead compounds and commercial outcomes that result from this effort. The joint venture is focused on the discovery and development of novel, small molecule, broad-spectrum antibacterials.

The venture combines our validated targets, assays and compound profiling capabilities with ArQule's Parallel Track™ Drug Discovery platform. Under the terms of the agreement, we will contribute a number of proprietary validated targets and ArQule will contribute its compound libraries and medicinal chemistry capabilities. Both companies are involved in screening efforts. It is anticipated that we will develop compounds through early clinical testing and then make a decision on a potential partnership with a larger pharmaceutical company.

To date, 12 targets have been screened, several chemical series are undergoing further characterization and four (4) promising lead candidates from two (2) chemotypes have been tested in vivo.

Internal Drug Discovery

Bacterial and Fungal Infections

We continue to invest in developing targets and downstream discovery capabilities in bacterial and fungal infections. These efforts are focused in three program areas:

Essential Microbial Targets - We are seeking to discover both broad and narrow

spectrum anti-microbial agents. We are mining the sequence information contained in our PathoGenome™ Database to identify genes that are conserved in a broad or narrow spectrum of pathogens. We concentrate on conserved microbial genes that have low homology with human genes to decrease risk of toxicity in man. Using our proprietary functional genomics technology, our scientists have been able to discover among these conserved genes, genes that are essential for the survival of pathogenic organisms. Thus, our gene discovery approach generates validated essential microbial targets that possess both selectivity and specificity, which are ideal attributes for drug intervention. These targets serve as the basis for our internal drug discovery efforts. In this regard, we have drawn upon our strengths in microbial genetics to develop both biochemical and cell based assays for these targets for use in our high-throughput screening platform. In addition, we continue to build internal capabilities through the acquisition of novel compound libraries. We anticipate that these efforts will lead to the further growth of our own infectious disease franchise. We may enter into alliances with other companies to engage in the development, commercialization

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and marketing of leads identified through this program.

Biofilms - A biofilm is a structured community of bacterial cells enclosed in a

self-produced polymeric matrix and adherent to an inert or living surface. Biofilms constitute a protected mode of growth that allow survival in a hostile environment. The Centers for Disease Control has estimated that up to 65% of the infections treated by physicians in the developed world are caused by organisms growing in this protected mode of growth. Bacterial biofilms are inherently resistant to antibiotics. Among the approximately 5 million Central Venous Catheter (CVCs) and pulmonary arterial catheters (Swan-Ganz) placed in the US per year, as many as 10% of these lines become infected, resulting in about 200,000 to 400,000 episodes of catheter-related bloodstream infections. Discovering how biofilm formation and detachment are controlled may open the way to new anti-microbial therapeutic strategies that may become more important than agents designed to kill bacterial cells. We are applying our microbial genomics and functional genomics platforms to identify genes involved in biofilm formation, maturation and degradation. After further validation, genes will progress to high-throughput screening to identify lead candidates for further development.

Chronic Human Diseases

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We have developed an integrated suite of technologies, tools and data management and analysis capabilities to discover genes associated with human disease. We have developed sophisticated techniques for evaluating families whose members suffer from diseases with a significant inherited component. Our scientists carefully characterize human phenotypes and develop linkage maps to discover genes associated with human disease. Our human disease drug discovery platform uses a well developed yeast-2 hybrid capability, bioinformatics and microarrays to elucidate the protein pathways of the genes we discover. This approach enables us to find multiple targets for screening. Our asthma alliance advanced into high throughput screening during the last 12 months.

We plan to continue to invest in our human gene discovery program. We are evaluating a number of families who are affected by chronic diseases with a strong inherited component. By gaining access to these families and analyzing their history and their genetics, we are able to discover disease-associated genes. Additionally, we continue to invest in functional genomics technologies to help determine gene function.

We plan to continue to partner all of our programs in human diseases with major pharmaceutical companies. These companies have the biological and disease expertise, the clinical development capabilities and the sales and marketing infrastructure required to discover and develop new drugs in these areas.

GENOMEVISON(TM) SERVICES

In addition to our drug discovery programs, we have built a successful service business for genomics-based research that provides industrial scale, high quality a) library construction; b) customized sequencing services; c) confirmation sequencing; d) project finishing, assembly and annotation; e) SNP discovery and screening; and, f) quality control testing & validation to pharmaceutical companies, biotechnology companies, and research institutions on a contract basis. Since the launch of these services in July 1999, we have entered into many contracts with pharmaceutical and biotechnology companies and other research institutions, in addition to our longstanding work in the United

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States government's genomics programs.

We have extensive experience in high-throughput sequencing with a substantial production staff and a highly automated sequencing center operating twenty-four hours per day, seven days per week. The U.S. government recognized the quality of our sequencing work by naming us as one of ten U.S. centers for the Human Genome Project and one of two primary centers for the Rat Genome Sequencing Program. We were the only commercial entity selected for the Human Genome Project.

National Human Genome Research Institute

In July 1999, the U.S. government named us one of five NIH funded DNA sequencing centers in the U.S. for the international Human Genome Project. The government based the award on a peer review process that evaluated our industrial scale sequencing facility for production capacity, cost effectiveness and quality standards. We are the only commercial entity to have been chosen to participate in the project. We will receive funding from the NHGRI of up to \$17.4 million through February 2003, of which all funds have been appropriated.

In October 1999, the U.S. government named us as one of ten initial centers in the Mouse Genome Sequencing Network. The government based the award on a peer review process that evaluated our industrial scale sequencing facility for production capacity, cost effectiveness and quality standards. The NHGRI agreed to provide us with funding of up to \$13.4 million through February 2003, of which all funds have been appropriated. In August 2000, we were named as one of two primary centers for the Rat Genome Sequencing Program and agreed to switch its research focus from the Mouse Program to the Rat Program. Remaining funds from the Mouse Program, as well as a portion of the remaining funds from the Human Genome Project, are being redirected to the Rat Genome Sequencing Program.

Under both these research contracts, the U.S. government has ownership rights to the data, clones, genes and other material derived from material furnished to us by the government. We have ownership rights in other inventions that we develop on our own under the contracts.

PathoGenome(TM) Database

In 1997, we introduced to the market the PathoGenome Database, a database consisting of proprietary and publicly available genetic information from over thirty microbial organisms, including organisms responsible for the most prevalent bacterial infections. The PathoGenome Database provides subscribers with non-exclusive access to a large volume of highly organized and functionally annotated sequence information related to some of the most medically important microbial organisms and fungi. We initially designed

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the PathoGenome Database to be accessed at the client site using our proprietary bioinformatics software. It enables researchers to search for new genes among multiple pathogens and cross-reference genomic information for the development of new anti-infective products.

Our Technology

We have created an integrated high quality platform of drug discovery technologies. This platform includes high quality, industrial scale gene sequencing and sequence finishing, bioinformatics, functional genomics technologies, assay development, high throughput screening and compound profiling.

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High-Throughput Gene Sequencing

We have developed a high-quality, industrial scale process for gene sequencing. Our GenomeVision(TM) Services utilize a fully automated process that makes use of DNA sequencing instruments and computers to sequence and analyze genes. We maintain high quality standards for all steps of our sequencing process by strictly controlling the quality of the raw data generated. Using our technology, we have sequenced and continue to sequence the genomes of bacterial and fungal pathogens and various regions of the human, rat and other genomes. We were the only commercial company that participated in the Human Genome Project.

Sequence Finishing

Finishing is the final step to organizing the genomic data once the majority of the sequence information has been generated. Finishing is necessary because the individual clones sequenced contain small, randomly selected fragments of the complete genome. We assemble these fragments using sophisticated proprietary computer software that identifies overlapping regions and arranges the fragments into large contiguous regions. We also employ a directed sequencing approach in order to specifically target and obtain sequences for the missing regions to facilitate completion of the full genome sequence. We have developed a proprietary finishing platform that utilizes integrated computational and biochemical approaches to specify the required quality of the end-product sequence and then directs the process to achieve the desired quality level. As a result of our emphasis on quality, we currently have a finished data accuracy of 99.99%.

Bioinformatics

Vast amounts of data result from DNA sequencing, finishing, microarray and other genomic technologies that we employ. In order to determine the biological significance and function of the genomic data that we compile, it must be organized, managed, and analyzed. Bioinformatics involves the use of computers, software, and databases to track, process, store, retrieve and analyze data generated by genomic research. We were one of the first companies to develop a significant bioinformatics capability due to our early work in large-scale genetic linkage and sequence analysis. A central focus of our current bioinformatics program is the development of an integrated genomic and functional genomic data management platform to strengthen and accelerate our gene and drug discovery programs. The objective of our bioinformatics program is to accelerate the discovery of genes and the determination of their function.

Functional Genomics

Functional genomics is the process of assigning biochemical functions and disease roles to genes. In the target discovery and validation stages of our pharmaceutical and diagnostic programs, functional genomics confirms that specific gene targets are appropriate for the development of pharmaceutical, vaccine, or diagnostic products. We have developed a number of technologies to accelerate the functional analysis of important disease genes, including gene expression, micro arrays, protein-protein interaction technologies and gene knockouts. When we combine our expertise in bioinformatics with these technologies, we bridge the gap between gene discovery and drug discovery.

High Throughput Screening & Compound Libraries

We have built a high-throughput screening capability to test compounds against validated targets. Our screening technologies allow us to develop biochemical and cell-based screening assays and screen. The output of each screen is captured in our central database using our cheminformatics tools. We have built a diverse compound library of over 80,000 compounds acquired from

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commercial sources. We use cheminformatics to select compounds based on their diversity and several "drug-like" properties. During

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2001, our first full year of operation, we screened our libraries against multiple targets generating over 2.2 million datapoints.

Patents and Proprietary Technology

Our ultimate commercial success depends in part on our ability to obtain intellectual property protection on our methods, technologies and discoveries, including genes, proteins encoded by genes, patentable human single nucleotide polymorphisms (SNPs), haplotypes or products based on genes or our proprietary gene technology. To that end, our policy is to protect our proprietary technology primarily through patents, in spite of the fact that the current criteria for obtaining patent protection for partially sequenced genes and for genes are unclear. Our current strategy is to apply for patent protection upon the identification of a novel gene or novel gene fragment and pursue claims to these gene sequences as well as equivalent sequences, such as substantially homologous or orthologous sequences. If at the time of filing a patent application we have not characterized the biological function of a gene or gene fragment we supplement our patent filing as soon as additional biological function information about such gene or gene fragment becomes available.

We have filed patent applications and will continue to do so with respect to a number of full-length genes and corresponding proteins and partial genes resulting from our pathogens program. Along with our collaborators, we file foreign counterparts of these U.S. applications within the appropriate time frames. Our patent applications seek to protect these full length and partial gene sequences and corresponding proteins, as well as equivalent sequences, and products derived from and uses of these sequences.

There have been, and continue to be, intensive discussions on the scope of patent protection for gene fragments, single nucleotide polymorphisms, and full-length genes. In 1996, the U.S. Patent and Trademark Office issued guidelines limiting the number of nucleic acid sequences that can be covered in a single patent application. In addition, the U.S. courts continue to redefine and narrow the enforceable scope of claims to genes, gene fragments, SNPs, and proteins. The U.S. PTO also issued new Utility Guidelines that address the requirements for demonstrating utility, particularly in inventions relating to human therapeutics, and Written Description guidelines that address the amount of disclosure required to support claims to nucleotide sequences. Consequently, we continually must assess our patent applications to determine those that we can support for prosecution.

While the guidelines do not require clinical efficacy data for issuance of patents for human therapeutics, the guidelines have been in effect for only a short period of time and it is possible that the U.S. PTO may interpret them in a way that could delay or adversely affect our ability or the ability of our collaborators to obtain patent protection. The biotechnology patent situation outside the United States is even more uncertain and is currently undergoing review and revision in many countries.

We are free to apply for patents on the results of our research conducted with government funds. Under the government grants, subject to the limitations described below, we have exclusive ownership rights to any commercial applications of inventions that we first reduce to practice under the grants, including all gene discoveries and technology improvements created or discovered. We are under an obligation under some of the government grants to

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submit sequencing data resulting from the research to public databases within 24 hours from the date we generate such data and materials. The governmental grants also restrict us from applying for blanket patents on large numbers of human or mouse genes. In addition, the government has a statutory right to practice or permit others to practice inventions that we first reduce to practice under a government grant or contract. In addition, under our government research contracts, the government has ownership rights in the data, clones, genes and other material derived from the material the government furnished to us.

The patent positions of biotechnology and pharmaceutical companies are generally uncertain and involve complex legal and factual issues. No assurance can be given that any patent issued to or licensed by us or our collaborators will provide protection that has commercial significance. We cannot assure that:

- . our patents will afford protection against competitors with similar compounds or technologies
- . our patent applications will issue
- . others will not obtain patents having claims similar to the claims in our patents or applications
- . the patents of others will not have an adverse effect on our ability to do business or
- . the patents issued to or licensed by us will not be infringed, challenged, opposed, narrowed, invalidated or circumvented

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Moreover, we believe that obtaining foreign patents may, in some cases, be more difficult than obtaining domestic patents because of differences in patent laws. We also recognize that our patent position may generally be stronger in the U.S. than abroad.

In particular, we are aware that companies have published patent applications relating to nucleic acids encoding several *H. pylori* proteins and, in other disease programs, relating to genes for which we have found mutations of interest. If these companies are issued patents, their patents may limit our ability and the ability of our collaborators to practice under any patents that may be issued to us. Because of this, our collaborators or we may not be able to obtain a patent with respect to the genes of *H. pylori*. Further, the value of certain other patents issued to us or our collaborators that are the subject of other collaborations may be limited. Also, even if a patent were issued to our collaborators, or us, the scope of coverage or protection afforded to such patent may be limited.

We also rely upon trademarks, unpatented trade secrets and improvements, unpatented know-how and continuing technological innovation to develop and maintain our competitive position. We generally protect this information with confidentiality agreements that provide that all confidential information developed or made known to others during the course of the employment, consulting or business relationship shall be kept confidential except in specified circumstances. Agreements with employees provide that all inventions conceived by the individual while employed by us are our exclusive property. We cannot guarantee, however, that these agreements will be honored, that we will have adequate remedies for breach if they are not honored or that our trade secrets will not otherwise become known or be independently discovered by competitors.

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Competition

The biotechnology industry generally, and our human genetics and pathogen genetics and drug discovery and development programs specifically, are characterized by rapidly evolving technology and intense competition. Our competitors include pharmaceutical and biotechnology companies both in the United States and abroad.

In addition, universities and other non-profit research institutions and United States and foreign government-sponsored entities are conducting significant research to identify and sequence genes. These entities are becoming more aggressive in their pursuit of patent protections and licensing arrangements. Many of these institutions and other consortia, such as the SNP Consortium, are also working to make large amounts of genetic information publicly available, shrinking the pool of information available for proprietary protection.

Many of our competitors have greater research and product development capabilities and financial, scientific, marketing and human resources than we do, and some competitors' human genome programs are more advanced than our program. Therefore, our competitors may succeed in identifying or sequencing genes or developing products earlier, in obtaining authorization from the FDA for products more rapidly and in developing products that are more effective than those proposed by our collaborators or us. Any potential products based on genes that we identify will face competition both from companies developing gene-based products and from companies developing other forms of diagnosis or treatment for the particular diseases.

Accordingly, competition with respect to our technologies and product candidates is and will be based on, among other things:

- . our ability to create and maintain advanced technology
- . the speed with which we can identify and characterize the genes involved in human diseases
- . our ability to rapidly sequence the genomes of selected pathogens
- . our ability and our partners' ability to develop and commercialize therapeutic, vaccine and diagnostic products based upon our gene discoveries
- . our ability to attract and retain qualified personnel
- . our ability to obtain patent protection
- . our ability to develop proprietary technology or processes
- . our ability to secure sufficient capital resources to fund our research operations
- . our ability to successfully manage the clinical development and registration of our product

We also face increasing competition for strategic alliances with leading pharmaceutical and biotechnology companies. We cannot be certain that we will be able to obtain such strategic alliances in the future or that we will be able to obtain them on terms comparable with existing alliances. Competition among

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genetics companies is also increasing for access to unique data from related individuals that we employ to identify genes for specific human diseases. We also face increasing competition for in-licensing opportunities with leading pharmaceutical and biotechnology companies. We cannot be certain that we will be able to in-license product opportunities in the future.

Our competitive position will also depend upon our ability to attract and retain qualified personnel, to obtain patent protection or otherwise develop proprietary product or processes, and to secure sufficient capital resources for the often-substantial period between technological conception and commercial sales. Competitive disadvantages in any of these areas could materially harm our business and financial condition.

Government Regulation

Regulation by governmental entities in the United States and other countries will be a significant factor in the development, manufacturing and marketing of any products that our collaborators or we develop. The extent to which such regulation may apply to our collaborators or us will vary depending on the nature of the product. Virtually all of our or our collaborators' pharmaceutical products will require regulatory approval by governmental agencies prior to commercialization. In particular, the FDA in the United States and similar health authorities in foreign countries subject human therapeutic and vaccine products to rigorous preclinical and clinical testing and other approval procedures. Various federal and, in some cases, state statutes and regulations also govern or influence the manufacturing, safety, labeling, storage, record keeping and marketing of human therapeutic and vaccine products. Obtaining these approvals and complying with appropriate federal and foreign statutes and regulations requires a substantial amount of time and financial resources.

The FDA regulates human therapeutic products in one of three broad categories: drugs, biologics, or medical devices. Our most advanced product, Ramoplanin, will be regulated by the Center for Drug Evaluation and Research (CDER). Products discovered based on our technologies could potentially fall into all three categories. The FDA generally requires the following steps for pre-market approval of a new drug or biological product:

- . preclinical laboratory and animal tests
- . submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical trials may begin
- . adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for its intended indication
- . submission to the FDA of a marketing application; a new drug application, or NDA, if the FDA classifies the product as a new drug; or a biologics license application, or BLA, if the FDA classifies the product as biologic
- . FDA review of the marketing application and NDA or BLA in order to determine, among other things, whether the product is safe and effective for its intended uses

Our collaborators or we also may develop diagnostic products based upon the human or pathogen genes that we identify. We believe that the FDA is likely to regulate these diagnostic products as devices rather than drugs or biologics. The nature of the FDA requirements applicable to diagnostic devices depends on how the FDA classifies the diagnostic devices. The FDA most likely will classify a diagnostic device that our collaborators or we develop as a Class III device, requiring pre-market approval. Obtaining pre-market approval involves the following process, which may be costly and time-consuming:

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- . conducting pre-clinical studies
- . obtaining an investigational device exemption to conduct clinical tests
- . conducting clinical trials
- . filing a pre-market approval application
- . attaining FDA approval

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Products on the market are subject to continual review by the FDA; therefore, subsequent discovery of previously unknown problems, or failure to comply with the applicable regulatory requirements may result in restricted marketing or withdrawal of the product from the market and possible civil or criminal sanctions. The FDA also may subject biologic products to batch certification and lot release requirements. To the extent that any of our products involve recombinant DNA technology, additional layers of government regulation and review are possible. Similarly, there are additional regulatory requirements for products marketed outside the United States governing the conduct of clinical trials, product licensing, pricing and reimbursement.

Manufacturing and Marketing

We do not expect to manufacture pharmaceutical products in the near term. The terms of our agreement for Ramoplanin obligate the licensor, Biosearch Italia SpA. to manufacture the bulk drug. We are responsible for the manufacture of the finished dosage form for the United States and Canada. We currently use a contract manufacturer to produce Ramoplanin for our clinical trial program. We plan to also use a contract manufacturer to produce the final dosage to support product sales. In the event we decide to establish a manufacturing facility of our own, we will require substantial additional funds and will need to hire and train significant additional personnel and will need to comply with the extensive "good manufacturing practice" regulations applicable to such a facility. In addition, if the FDA regulated any products produced at our facility as biologics, we would need to file and obtain approval of an Establishment License Application for our facility.

Our current plan is to market and sell Ramoplanin through our own sales and marketing organization. We may, at a later date, determine that the commercial success of Ramoplanin will benefit from the additional resources from a pharmaceutical marketing partner would provide. We currently do not have the resources to market by ourselves, but fully expect to assemble a sales and marketing organization at the appropriate time.

Factors That May Affect Results

This Annual Report on Form 10-K contains forward-looking statements. For this purpose, any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words "believes," "anticipates," "plans," "expects," "intends," and similar expressions are intended to identify forward-looking statements. There are a number of important factors that could cause our actual results to differ materially from those indicated by such forward-looking statements. Those factors include, without limitation, those set forth throughout this Annual Report on Form 10-K, including the risks detailed in Exhibit 99.1 to this Annual Report on Form 10-K.

Human Resources

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As of December 31, 2001, we had 204 full-time equivalent employees; of which 167 of these employees engaged in research and development activities and 37 of them conducted general and administrative functions. Forty-four of our employees hold Ph.D. degrees and 50 more hold other advanced degrees.

None of our employees is covered by a collective bargaining agreement, and we consider our relations with our employees to be good.

Facilities

Our executive offices and laboratories are located at 100 Beaver Street, Waltham, Massachusetts. We lease approximately 80,000 square feet of space and our lease expires on November 15, 2006 with options to extend for two consecutive five-year periods. During 2001, we incurred aggregate rental costs, excluding maintenance and utilities, for our facility of approximately \$1,007,000.

ITEM 3. Legal Proceedings

None.

ITEM 4. Submission Of Matters to a Vote of Security Holders

None.

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PART II

ITEM 5. Market for the Registrant's Common Stock and Related Security Holder Matters

Our common stock is traded on the Nasdaq National Market System (ticker symbol "GENE"). The table below sets forth the range of high and low quotations for each fiscal quarter during 2001 and 2000 as furnished by the National Association of Securities Dealers Quotation System.

	2001		2000	
	High	Low	High	Low
First Quarter.....	\$ 11.690	\$ 4.750	\$ 75.380	\$ 11.440
Second Quarter.....	16.900	4.781	39.000	11.440
Third Quarter.....	15.450	4.010	34.500	11.440
Fourth Quarter.....	8.390	5.450	21.440	11.440

As of March 27, 2002, there were approximately 1,018 shareholders of record of our common stock.

We have not paid any dividends since our inception and presently anticipate that all earnings, if any, will be retained for development of our business and that no dividends on our common stock will be declared in the foreseeable future. Any future dividends will be subject to the discretion of our Board of Directors and will depend upon, among other things, future earnings, the operating and financial condition of the Company, our capital requirements and

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general business conditions.

ITEM 6. Selected Consolidated Financial Data

	For the Year Ended December 31			
	1997	1998	1999	2000
Revenues:				
BioPharmaceutical	\$ 11,132,294	\$ 18,135,038	\$ 18,162,056	\$ 11,8
GenomeVision(TM) Services	3,300,881	3,913,376	6,665,529	13,5
Total revenues	14,433,175	22,048,414	24,827,585	25,4
Net loss.....	(16,031,795)	(12,967,676)	(3,940,075)	(5,8
Net loss per common share.....	(0.90)	(0.71)	(0.21)	
Weighted average common shares outstanding	17,771,824	18,289,644	18,627,045	21,3

As of December 31,

As of December 31,				
Cash and cash equivalents, restricted cash, warrant and long and short-term investments.....	\$ 44,492,461	\$ 30,816,859	\$ 26,778,026	\$ 73,0
Working capital.....	31,298,804	19,749,608	19,447,189	51,6
Total assets.....	61,230,003	48,920,973	45,443,236	90,2
Shareholders' equity.....	40,089,689	27,557,237	28,846,957	72,6

ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

OVERVIEW

We are a biopharmaceutical company focused on the discovery and development of pharmaceutical and diagnostic products. We have eight established product development programs. Our lead product candidate, Ramoplanin, is in Phase III clinical trials for the prevention of bloodstream infections caused by vancomycin-resistant enterococci (VRE). We have six alliances with pharmaceutical companies including Schering-Plough, AstraZeneca, Wyeth-Ayerst and bioMerieux, and a joint venture with ArQule. In addition to these eight projects, we have a portfolio of earlier stage internal drug discovery programs. We also maintain an active service business, GenomeVision(TM) Services, providing drug discovery services to pharmaceutical and biotechnology companies and to the National Human Genome Research Institute.

We receive payments under our bioPharmaceutical business from our product discovery alliances based on license fees, contract

research and milestone payments during the term of the alliance. We also receive payments under our GenomeVision Services business from selling, as a contract service business, high quality genomic sequencing information to our

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customers, including pharmaceutical companies, biotechnology companies, governmental agencies, and academic institutions. In addition, under our GenomeVision Services business, subscribers to our PathoGenome(TM) Database pay access fees for the information they obtain. We anticipate that our alliances will result in the discovery and commercialization of novel pharmaceutical, vaccine and diagnostic products. In order for a product to be commercialized based on our research, it will be necessary for our product discovery partner to conduct preclinical tests and clinical trials, obtain regulatory clearances, manufacture, sell, and distribute the product. Accordingly, we do not expect to receive royalties based upon product revenues for many years, if at all.

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 six product discovery alliances and one joint venture, of which we currently receive contract research funding from three of these alliances. In August 1995, we entered into an alliance with AstraZeneca to develop pharmaceutical, vaccine and diagnostic products effective against gastrointestinal infections or any other disease caused by *H. pylori*. In August 1999, the contract research under the alliance concluded and the program transitioned into AstraZeneca's pipeline. We are entitled to receive additional milestone payments and royalties based upon the development by AstraZeneca of any products from the research alliance. In December 1995, we entered into an alliance with Schering-Plough. Under this alliance, Schering-Plough can use our *Staph. aureus* genomic database to identify new gene targets for the development of novel antibiotics. As of December 31, 2001, we had substantively completed our research obligations under this alliance and had turned over validated drug targets and assays to Schering-Plough for high-throughput screening. In December 1996, we entered into our second research alliance with Schering-Plough to identify genes and associated proteins that Schering-Plough can utilize to develop new pharmaceuticals for treating asthma. In September 1997, we established our third research alliance with Schering-Plough for the development of new pharmaceutical products to treat fungal infections. As of December 31, 2001, we had substantively completed our research obligations under this alliance and had turned over validated drug targets and assays to Schering-Plough for high-throughput screening. In September 1999, we entered into a strategic alliance with bioMerieux to develop, manufacture and sell in vitro pathogen diagnostic products for human clinical and industrial applications. As part of the strategic alliance, bioMerieux has purchased a subscription to our PathoGenome Database and has 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 September 2000, we entered into a joint venture with ArQule, Inc. to identify novel anti-infective drug compounds.

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 December 31, 2001, we had 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 potential for royalty payments to us from future product sales. We do expect to see a revenue decline in subscription fees over the next two years as subscribers substantially complete data mining of PathoGenome.

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, we were named as one of the nationally funded DNA sequencing centers of the international Human Genome Project. We are entitled to receive funding from the National Human

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Genome Research Institute (NHGRI) of up to \$17.4 million through February 2003, of which all funds have been appropriated and \$12.0 million had been received through December 31, 2001. In October 1999, the NHGRI named us as a pilot center to the Mouse Genome Sequencing Network. We are entitled to receive \$13.4 million in funding over forty-one months with respect to this agreement, of which all funds have been appropriated and \$10.4 million had been received through December 31, 2001. In August 2000, we were 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.

In October 2001, we acquired an exclusive license in the United States and Canada for a novel antibiotic, Ramoplanin, from Biosearch Italia S.p.A (Biosearch). 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 will retain all other rights to market and sell Ramoplanin. In addition, we are obligated to purchase bulk material from Biosearch and fund the completion of clinical trials, purchase bulk material, and pay a royalty on product sales. The combined total of bulk product purchases and royalties is expected to be approximately 26% of our net product sales.

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We have incurred significant operating losses since our inception. As of December 31, 2001, we had an accumulated deficit of approximately \$82.1 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 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, uncertainty of regulatory approval, uncertainty of pharmaceutical pricing, rapid technological change, history of operating losses, need for future capital, competition, patent and proprietary rights, dependence on key personnel, healthcare reform and related matters, availability of, and competition for, unique family resources, and volatility of our stock.

NEW ACCOUNTING PRONOUNCEMENTS

In June 2001, the Financial Accounting Standards Board (FASB) issued SFAS No. 141, Business Combinations, SFAS No. 142, Goodwill and Other Intangible Assets and SFAS No. 143, Accounting for Asset Retirement Obligations. SFAS No. 141 requires that all business combinations initiated after June 30, 2001 be accounted for using the purchase method of accounting. SFAS No. 142 addresses 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 SFAS 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 SFAS No. 142 are required to be applied starting with fiscal years beginning after December 15, 2001. SFAS No. 143 establishes accounting standards for the recognition and

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measurement of legal obligations associated with the retirement of tangible long-lived assets and requires recognition of a liability for an asset retirement obligation in the period in which it is occurred. SFAS No. 143 is effective for fiscal years beginning after June 15, 2002. The adoption of SFAS No. 142 did not have a material impact on the Company's financial position or results of operations. The adoption of SFAS No. 143 is not expected to have a material impact on the Company's 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 Accounting Principles Board (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 the adoption of this Statement to have a material impact on its financial position or results of operations.

CRITICAL ACCOUNTING POLICIES

In December 2001, the SEC requested that reporting companies discuss their most "critical accounting policies" in management's discussion and analysis of financial condition and results of operations. The SEC indicated that a "critical accounting policy" is one that is important to the portrayal of a company's financial condition and operating results and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain.

We have identified the policies below as critical to our business operations and the understanding of our results of operations. The impact and any associated risks related to these policies on our business operations is discussed throughout Management's Discussion and Analysis of Financial Condition and Results of Operations where such policies affect our reported and expected financial results. For a detailed discussion on the application of this and other accounting policies, see Note 1 in the Notes to the Consolidated Financial Statements of this Annual Report on Form 10-K. The Company's preparation of this Annual Report on Form 10-K requires it to make estimates and assumptions that affect the reported amount of assets and liabilities, disclosure of contingent assets and liabilities at the date of its financial statements, and assurance that actual results will not differ from those estimates.

Revenue Recognition

BioPharmaceutical revenues consist of license fees, contract research and milestone payments from alliances with pharmaceutical

companies. GenomeVision Services are revenues from government grants, fees received from custom gene sequencing and analysis services and subscription fees from the PathoGenome Database. Revenues from contract research, government grants, the PathoGenome Database subscription fees, and custom gene sequencing

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and analysis services are recognized over the respective contract periods as the services are provided. License fees and milestone payments are recognized as earned in accordance with Staff Accounting Bulletin (SAB) No. 101, Revenue Recognition. Milestone payments will be recognized upon achievements of the milestone as long as the milestone is deemed to be substantive and we have no other performance obligations related to the milestone. Unbilled costs and fees represent revenue recognized prior to billing. Deferred revenue represents amounts received prior to revenue recognition.

Clinical Trial Estimates

Our clinical development trials related to Ramoplanin are primarily performed by outside parties. It is not unusual at the end of each accounting period to estimate both the total cost of the trials and the percent completed as of that accounting date. We then need to adjust our estimates when final invoices are received. To date, these adjustments have not been material to our financial statements, and we believe that the estimates that we made as of December 31, 2001 are reflective of the actual expenses incurred as of that date. However, readers should be cautioned that the possibility exists that the timing or cost of certain trials might be longer or shorter and cost more or less than we have estimated and that the associated financial adjustments would be reflected in future periods.

Results of Operations

Years Ended December 31, 2000 and 2001

Revenues

Total revenues increased 40% from \$25,445,000 in 2000 to \$35,741,000 in 2001. BioPharmaceutical revenue increased 56% from \$11,851,000 in 2000 to \$18,438,000 in 2001 primarily due to increased milestone payments under our product discovery alliances with Wyeth-Ayerst and Schering-Plough.

Revenue from GenomeVision Services increased 27% from \$13,594,000 in 2000 to \$17,302,000 in 2001 due to increased revenue recognized under our commercial sequencing business of approximately \$935,000, as well as increased revenue recognized under our government grants with the National Human Genome Research Institute to participate in the Human Genome and Mouse (Rat) Genome sequencing projects of approximately \$3,175,000.

Costs and Expenses

Total costs and expenses increased 45% from \$33,780,000 in 2000 to \$48,978,000 in 2001. Cost of services increased 39% from \$11,715,000 in 2000 to \$16,153,000 in 2001 primarily due to increased costs and expenses associated with the increase in GenomeVision Services revenue, as mentioned above. The increase consisted primarily of higher labor and material costs.

Research and development expenses include internal research and development, research funded pursuant to arrangements with our strategic alliance partners, as well as clinical development costs and expenses. Research and development expenses increased 58% from \$15,191,000 in 2000 to \$24,058,000 in 2001. This planned increase was primarily due to the acquisition and clinical development of Ramoplanin of approximately \$5,549,000, as well as increased investment in our internal drug discovery programs, specifically in the area of anti-infectives and chronic human diseases of \$4,138,000.

Selling, general and administrative expenses increased 28% from \$6,875,000 in 2000 to \$8,767,000 in 2001 reflecting an expansion in the areas of corporate development, sales and marketing and clinical development administrative expenses. The increase consisted of an increase in payroll and related expenses,

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as well as recruiting and consulting expenses.

Interest Income and Expense

Interest income increased 15% from \$3,331,000 in 2000 to \$3,839,000 in 2001 reflecting an increase in funds available for investment as a result of (i) proceeds received from the sale of common stock through a public offering in 2000 and 2001, (ii) proceeds received from the exercise of stock options, and (iii) proceeds received from our employee stock purchase plan.

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Interest expense decreased 18% from \$843,000 in 2000 to \$692,000 in 2001. The decrease was due to a decrease in our outstanding balances under long-term obligations from approximately \$7.8 million at December 31, 2000 to \$5.6 million at December 31, 2001.

Years Ended December 31, 1999 and 2000

Revenues

Total revenues increased slightly by 2% from \$24,828,000 in 1999 to \$25,445,000 in 2000. BioPharmaceutical revenue decreased 35% from \$18,162,000 in 1999 to \$11,851,000 in 2000 primarily due to decreased contract research revenue and milestone payments under our product discovery alliances.

Revenue from GenomeVision Services increased 104% from \$6,665,000 in 1999 to \$13,594,000 in 2000 primarily due to increased revenue recognized under our commercial sequencing business of approximately \$691,000, as well as increased revenue recognized under our government grants with the National Human Genome Research Institute to participate in the Human Genome and Mouse (Rat) Genome sequencing projects of approximately \$6,779,000.

Costs and Expenses

Total costs and expenses increased 15% from \$29,389,000 in 1999 to \$33,780,000 in 2000. Cost of services increased 157% from \$4,560,000 in 1999 to \$11,715,000 in 2000 primarily due to increased costs and expenses associated with the increase in GenomeVision Services revenue, as mentioned above. The increase consisted primarily of higher labor and material costs.

Research and development expenses include internal research and development, research funded pursuant to arrangements with our strategic alliance partners, as well as clinical development costs and expenses. Research and development expenses decreased 25% from \$20,376,000 in 1999 to \$15,191,000 in 2000. This reduction in research and development expenses was primarily attributable to a decline in our internal drug discovery programs and research funded under our product discovery alliances during 2000.

Selling, general and administrative expenses increased 54% from \$4,453,000 in 1999 to \$6,875,000 in 2000 primarily due to increases in payroll and related expenses, non-cash charges related to the issuance of stock options and restricted stock awards, as well as increased shareholder communication expenses caused by an expanded shareholder base.

Interest Income and Expense

Interest income increased 124% from \$1,488,000 in 1999 to \$3,331,000 in 2000 reflecting primarily an increase in funds available for investment as a result of (i) proceeds received from the sale of common stock through a public

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offering in 2000, (ii) proceeds received from the exercise of stock options, and (iii) proceeds received from our employee stock purchase plan.

Interest expense decreased 3% from \$867,000 in 1999 to \$843,000 in 2000. The decrease was due to a decrease in our outstanding balances under long-term obligations from approximately \$8.9 million at December 31, 1999 to \$7.8 million at December 31, 2000.

Liquidity and Capital Resources

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

As of December 31, 2001, we had cash, cash equivalents, restricted cash and short-term and long-term investments of approximately \$67,341,000. In 2001, we sold 127,500 shares of common stock in a series of transactions through the Nasdaq National Market, resulting in proceeds received of approximately \$1,706,000, net of issuance costs. In 2001, we also issued 352,950 shares of common stock related to the exercise of stock options and our employee stock purchase plan, resulting in proceeds received of approximately \$1,204,000. In 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. In 2000, we issued 1,288,943 shares of common stock related to the exercise of stock options and our employee stock purchase plan, resulting in proceeds received of approximately \$3,528,000.

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In 1999, we also sold 678,610 shares of common stock to bioMerieux, a product discovery partner, resulting in proceeds received of approximately \$3,732,000, net of issuance costs. In 1999, we also issued 472,459 shares of common stock related to the exercise of stock options, resulting in proceeds received of approximately \$1,235,000.

We received payments of approximately \$18,087,000, \$17,399,000 and \$22,866,000 in 2001, 2000 and 1999, respectively, from our product discovery partners consisting of up-front license fees, contract research funding, subscription fee, milestone payments and expense reimbursement.

We had various arrangements under which we financed certain office and laboratory equipment and leasehold improvements. We had an aggregate of approximately \$5,632,000 outstanding under our borrowing arrangements at December 31, 2001. This amount is repayable over the next 34 months, of which \$3,572,000 is repayable over 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. We had no additional borrowing capacity under these capital lease agreements at December 31, 2001. In February 2002, we entered into an additional line of credit for \$3,500,000, of which \$500,000 will be used to refinance a portion of the existing line of credit and the remaining \$3,000,000 to be used to finance office and laboratory equipment.

Our operating activities used cash of approximately \$3,091,000 in 2001 primarily due to an increase in our net loss and prepaid expenses and other assets, as well as a decrease in deferred revenue. These uses of cash were partially offset by a decrease in interest receivable, accounts receivable and unbilled costs and fees, as well as an increase in accounts payables and accrued

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liabilities. Our operating activities provided cash of approximately \$3,011,000 in 2000 and used cash of approximately \$1,616,000 in 1999.

Our investing activities provided cash of approximately \$20,017,000 in 2001 through the conversion of marketable securities to cash and cash equivalents, partially offset by purchases of marketable securities, equipment and additions to leasehold. Our investing activities used cash of approximately \$45,568,000 and \$2,467,000 in 2000 and 1999, respectively, to purchase marketable securities, equipment and additions to leasehold, partially offset the conversion of marketable securities to cash and cash equivalents.

Capital expenditures totaled \$3,706,000 during 2001 consisting of leasehold improvements and purchases of laboratory, computer, and office equipment. We utilized existing capital lease and equipment financing arrangements to finance the majority of these capital expenditures. We currently estimate that we will acquire approximately \$5,000,000 in capital equipment in 2002 consisting of primarily computers, laboratory equipment, and additions to leasehold improvement, which we intend to finance the majority of these purchases under new financing arrangements.

Financing activities used cash of approximately \$2,217,000 and \$205,000 in 2001 and 1999, respectively, primarily for payments of long-term obligations, partially offset by proceeds received from the sale of equity securities, exercise of stock options, and employee stock purchase plan. Financing activities provided cash of approximately \$43,636,000 in 2000 primarily from proceeds received from the sale of equity securities, exercise of stock options, and employee stock purchase plan, net of payments of long-term obligations.

At December 31, 2001, we had net operating loss and tax credits (investment and research) carryforwards of approximately \$93,767,000 and \$6,642,000, 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 carryforward period.

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

On March 6, 2002, we sold convertible debentures to two institutional investors in a private placement transaction, raising \$15 million in gross proceeds. The debentures may be converted into shares of our common stock at the option of the holder, at a price of \$8.00 per share, subject to certain adjustments. The maturity date of the debentures is December 31, 2004, provided, that if any time on or after December 31, 2003 the Company maintains a net cash balance (i.e., cash and cash equivalents less obligations for borrowed money bearing interest) of less than \$35 million, then the holders of the debentures can require that all or any part of the outstanding principal balance of the notes plus all accrued but unpaid interest be repaid. Interest on the debentures accrues at 6% annually. The investors also received warrants to purchase up to 487,500 shares of common stock at an exercise price of \$8.00 per share, subject to certain adjustments. The warrants only become exercisable to the extent the debentures are converted or if certain other redemptions or repayments of the debentures occur.

We plan to continue to invest in our internal research and development

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programs, including our lead candidate, Ramoplanin, currently in Phase III clinical development. We expect to incur \$15-20 million in Phase III clinical development expenditures through the end of 2002.

We expect to 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.

In 2000, we entered into two separate interest-rate-swap agreements with a bank aggregating approximately \$1,900,000. Under these agreements, we pay a fixed rate of 8.78% and receives a variable rate tied to the one month LIBOR rate. As of

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December 31, 2001, the variable rate was 3.83%. These swap agreements meet the required criteria, as defined in SFAS No. 133 to use special hedge accounting, and we have recorded an unrealized loss of \$30,830 at December 31, 2001, through other comprehensive income, for the change in the fair value of the swap agreements. At February 28, 2002, this debt had been paid off in its entirety and the interest-rate-swap agreements expired.

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-K 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 judgment 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 our ability and the ability of our alliance partners to (i) successfully develop products based on the Company's genomics information, (ii) obtain the necessary governmental approvals, (iii) effectively commercialize any products developed before our competitors and (iv) obtain and enforce intellectual property rights, as well as the risk factors set forth in this Annual Report on Form 10-K and those set forth in other filings that we may make with the Securities and Exchange commission from time to time.

ITEM 8. Financial Statements and Supplementary Data

Financial statements and supplementary data required by Item 8 are set forth at the pages indicated in Item 14(a) below.

ITEM 9. Disagreements on Accounting and Financial Disclosure

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None

PART III

Pursuant to General Instruction G(3) to Form 10K, the information required for Part III (Items 10, 11, 12, and 13) is incorporated herein by reference from the Company's proxy statement for the Annual Meeting of Shareholders to be held on June 25, 2002.

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PART IV

ITEM 14. Exhibits, Financial Statement Schedules and Reports on Form 8K

(a) FINANCIAL STATEMENTS AND FINANCIAL STATEMENT SCHEDULES (1) AND (2) See "Index to Consolidated Financial Statements and Financial Statement Schedules" appearing on page F-1.

(3) Exhibits

Exhibit No. -----	Description -----
3	Restated Articles of Organization and By laws /(1)/
3.1	Amendment dated January 5, 1982 to Restated Articles of Organization /(2)/
3.2	Amendment dated January 24, 1983 to Restated Articles of Organization /(3)/
3.3	Amendment dated January 17, 1984 to Restated Articles of Organization /(4)/
3.4	Amendment dated October 20, 1987 to the By-laws /(8)/
3.5	Amendment dated December 9, 1987 to Restated Articles of Organization /(9)/
3.6	Amendment dated October 16, 1989 to the By-law /(11)/
3.7	Amendment dated January 24, 1994 to Articles Restated Articles of Organization /(12)/
3.8	Amendment dated August 31, 1994 to Restated Articles of Organization /(14)/
3.9	Amendment dated March 15, 2001 to Restated Articles of Organization /(33)/
3.10	By-Laws of Genome Therapeutics Corp (as amended through July 24, 2001) /(34)/
4.2	Form of Note dated March 5, 2002 received by Smithfield Fiduciary LLC and the Tail
4.3	Form of Warrant received by Smithfield Fiduciary LLC and The Tail Wind Fund, Ltd.
10.4	Incentive Stock Option Plan and Form of Stock Option Certificate /(1)/
10.6	Genome Therapeutics Corp. (f/k/a Collaborative Research) Incentive Savings Plan /(1)/
10.7	Amendment dated November 4, 1986 to the Genome Therapeutics Corp. (f/k/a Collaborative Research) Incentive Savings Plan /(1)/

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- Plan dated March 1, 1985 /(7)/
- 10.14 1991 Stock Option Plan and Form of Stock Option Certificate /(12)/
- 10.15 Lease dated November 17, 1992 relating to certain property in Waltham, Massachusetts /
- 10.16 Lease dated June 3, 1993 relating to certain property in Waltham, Massachusetts /
- 10.19 Employment Agreement with Robert J. Hennessey /(13)/
- 10.22 Lease Amendment dated August 1, 1994 relating to certain property in Waltham, MA /
- 10.24 1993 Stock Option Plan and Form of Stock Option Certificate /(14)/
- 10.28 Agreement between the Company and AstraZeneca PLC (f/k/a Astra Hassle AB) dated Au
- 10.29 Collaboration and License Agreement between the Company, Schering Corporation and
December 6, 1995 /(18)/*
- 10.30 Form of director Stock Option Agreement and schedule of director options granted /
- 10.37 Lease amendment dated November 15, 1996 to certain property in Waltham, MA /(19)/
- 10.38 Collaboration and License Agreement between the Company, Schering Corporation and
December 20, 1996 /(20)/*
- 10.39 Credit agreement between the Company and Fleet National Bank dated February 28, 19
- 10.40 Credit agreement between the Company and U S Trust (f/k/a Sumitomo Bank, Limited)
- 10.41 Collaboration and License Agreement between the Company and Schering Corporation,
- 10.42 Collaboration and License Agreement between the Company and Schering-Plough Ltd. d
- 10.43 Credit modification agreement between the Company and Fleet National Bank, dated M
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- 10.44 1997 Directors' Deferred Stock Plan /(25)/
- 10.45 1997 Stock Option Plan /(25)/
- 10.46 Amended Employment Agreement with Robert J. Hennessey /(26)/
- 10.47 Collaboration and License Agreement between the Company and American Home Products,
Wyeth-Ayerst Division, dated December 20, 1999 /(27)/
- 10.49 Collaboration and License Agreement between Genome Therapeutics Corporation and bio
September 30, 1999 /(29)/
- 10.50 Registration Rights Agreement between the Company and bioMerieux Alliance sa dated
- 10.51 Compound Discovery Collaboration Agreement, dated October 17, 2000 between the Comp
- 10.52 2001 Incentive Plan /(32)/

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- 10.53 Stock Option Agreements with Steven M. Rauscher /(32)/
 - 10.55 Employment Letter with Steven M. Rauscher /(34)/
 - 10.56 Employment Letter with Stephen Cohen /(34)/
 - 10.57 Employment Letter with Richard Labaudinere PhD /(34)/
 - 10.58 Purchase Agreement dated March 5, 2002 among Smithfield Fiduciary LLC, The Tail Win
/(35)/
 - 10.59 Registration Rights Agreement dated March 5, 2002 among Smithfield Fiduciary LLC, T
Company /(35)/
 - 10.60 Employment Letter with Robert J. Hennessey /(36)/
 - 10.61 License and Supply Agreement between the Company and Biosearch Italia, S.P.A., date
 - 23. Consent of Arthur Andersen LLP Independent Public Accounts /(36)/
 - 99.1 Risk Factors /(36)/
 - 99.2 Letter to Commission Pursuant to Temporary Note 3T /(36)/
-

* Confidential treatment requested with respect to a portion of this Exhibit.

FOOTNOTES

/(1)/ Filed as exhibits to the Company's Registration Statement on Form S-1
(No. 2-75230) and incorporated herein by reference.

/(2)/ Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for
the quarter ended February 27, 1982 and incorporated herein by
reference.

/(3)/ Filed as exhibits to the Company's Quarterly Report on Form 10-Q for
the quarter ended February 26, 1983 and incorporated herein by
reference.

/(4)/ Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for
the quarter ended February 25, 1984 and incorporated herein by
reference.

/(6)/ Filed as an exhibit to the Company's Annual Report on Form 10-K for the
fiscal year ended August 31, 1985 and incorporated herein by reference.

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/(7)/ Filed as exhibits to the Company's Annual Report on Form 10-K for
the fiscal year ended August 31, 1986 and incorporated herein by
reference.

/(8)/ Filed as an exhibit to the Company's Annual Report on Form 10-K for
the year ended August 31, 1987 and incorporated herein by
reference.

/(9)/ Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for
the quarter ended November 28, 1987 and incorporated herein by

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reference.

- /(11)/ Filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended August 31, 1989 and incorporated herein by reference.
- /(12)/ Filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended August 31, 1992 and incorporated herein by reference.
- /(13)/ Filed as exhibits to the Company's Annual Report on Form 10-K for the fiscal year ended August 31, 1993 and incorporated herein by reference.
- /(14)/ Filed as exhibits of the Company's Annual Report on Form 10-K for the fiscal year ended August 31, 1994 and incorporated herein by reference.
- /(16)/ Filed as an exhibit to the Company's Annual Report on Form 10-K/A3 for the year ended August 31, 1995 and incorporated herein by reference.
- /(17)/ Filed as an exhibit to the Company Registration Statement on Forms S-8 (File No. 33-61191) and incorporated herein by reference.
- /(18)/ Filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended November 25, 1995 and incorporated herein by reference.
- /(19)/ Filed as an exhibit to the Company's 10-K for fiscal year ended August 31, 1996 and incorporated herein by reference.
- /(20)/ Filed as an exhibit to the Company's 10-Q/A for the quarter ended March 1, 1997 and incorporated herein by reference.
- /(21)/ Filed as an exhibit to the Company's 10-Q for the quarter ended May 31, 1997 and incorporated herein by reference.
- /(22)/ Filed as an exhibit to the Company's 10-K for fiscal year ended August 31, 1997 and incorporated herein by reference.
- /(23)/ Filed as exhibits to the Company's 10-Q for the quarter ended February 28, 1998 and incorporated herein by reference.
- /(24)/ Filed as an exhibit to the Company's 10-Q for the quarter ended May 30, 1998 and incorporated herein by reference.
- /(25)/ Filed as exhibits to the Company's Registration Statement on Forms S-8 (333-49069) and incorporated herein by reference.
- /(26)/ Filed as an exhibit to the Company's 10-K for fiscal year ended August 31, 1998 and incorporated herein by reference.
- /(27)/ Filed as an exhibit to the Company's 8-K filed on March 8, 2000 and incorporated herein by reference.
- /(29)/ Filed as an exhibit to the Company's 10-Q for the quarter ended November 27, 1999 and incorporated herein by reference.
- /(30)/ Filed as an exhibit to the Company's Registration Statement on Form S-3 (file No 333-32614) and incorporated herein by reference.
- /(31)/ Filed as an exhibit to the Company's 10-Q for the quarter ended November 25, 2000 and incorporated herein by reference.
- /(32)/ Filed as exhibit to the Company's Registration Statement on Form S-8 (333-58274) and incorporated herein by reference..

- /(33)/ Filed as an exhibit to the Company's 10-Q for the quarter ended February 24, 2001 and incorporated herein by reference.
- /(34)/ Filed as an exhibit to the Company's 10-Q for the quarter ended September 29, 2001 and incorporated herein by reference.
- /(35)/ Filed as an exhibit to the Company's 8-K filed on March 6, 2002 and incorporated herein by reference.
- /(36)/ Filed herewith.

GENOME THERAPEUTICS CORP. AND SUBSIDIARY
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Public Accountants.....

Consolidated Balance Sheets as of December 31, 2000 and 2001.....

Consolidated Statements of Operations for the Years Ended December 31, 1999, 2000 and 2001.....

Consolidated Statements of Shareholders' Equity and Comprehensive Income for the Years Ended December 31, 1999, 2000 and 2001.....

Consolidated Statements of Cash Flows for the Years Ended December 31, 1999, 2000 and 2001.....

Notes to Consolidated Financial Statements.....

REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To Genome Therapeutics Corp.:

We have audited the accompanying consolidated balance sheets of Genome Therapeutics Corp. and subsidiary (the Company) as of December 31, 2000 and 2001, and the related consolidated statements of operations, shareholders' equity and comprehensive income and cash flows for each of the three years in the period ended December 31, 2001. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated

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financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Genome Therapeutics Corp. and subsidiary as of December 31, 2000 and 2001, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2001 in conformity with accounting principles generally accepted in the United States.

/s/ Arthur Andersen LLP

Boston, Massachusetts
February 28, 2002

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GENOME THERAPEUTICS CORP. AND SUBSIDIARY CONSOLIDATED BALANCE SHEETS

	Decem
	----- 2000 -----
ASSETS	
Current Assets:	
Cash and cash equivalents.....	\$ 10,095,817
Short-term investments (held-to-maturity).....	51,743,917
Interest receivable.....	1,466,808
Accounts receivable.....	827,106
Unbilled costs and fees.....	796,072
Prepaid expenses and other current assets.....	900,547

Total current assets.....	65,830,267
	=====
Property and Equipment, at cost:	
Laboratory and scientific equipment.....	18,823,063
Leasehold improvements.....	8,302,308
Equipment and furniture.....	1,134,320

	28,259,691
Less--Accumulated depreciation.....	15,225,148

	13,034,543
Restricted Cash (Note 2).....	200,000
Long-term Investments (held-to-maturity).....	10,970,153
Warrant (available-for-sale).....	--
Other Assets.....	216,041

	\$ 90,251,004
	=====
LIABILITIES AND SHAREHOLDERS' EQUITY	

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Current Liabilities:	
Current maturities of long-term obligations.....	\$ 4,499,696
Accounts payable.....	1,296,511
Accrued expenses.....	3,712,757
Deferred revenue.....	4,720,234
Total current liabilities.....	14,229,198
Long-term Obligations, net of current maturities.....	3,334,354
Commitments (Note 4)	
Shareholders' Equity:	
Common stock, \$0.10 par value --	
Authorized -- 50,000,000 shares	
Issued and outstanding -- 22,288,658 and 22,772,170	
shares at December 31, 2000 and 2001, respectively.....	
	2,228,866
Additional paid-in capital.....	143,018,548
Accumulated deficit.....	(71,963,333)
Deferred compensation and note receivable from officer (Note 6(e)).....	(596,629)
Accumulated other comprehensive income.....	--
Total shareholders' equity.....	72,687,452
	\$ 90,251,004

The accompanying notes are an integral part of these consolidated financial statements.

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GENOME THERAPEUTICS CORP. AND SUBSIDIARY CONSOLIDATED STATEMENTS OF OPERATIONS

	Year E
	1999
Revenues:	
BioPharmaceutical.....	\$ 18,162,056
GenomeVision(TM) services.....	6,665,529
Total revenues	24,827,585
Costs and Expenses:	
Cost of services.....	4,559,588
Research and development.....	20,376,271
Selling, general and administrative.....	4,453,252
Total costs and expenses.....	29,389,111
Loss from operations.....	(4,561,526)
Interest Income (Expense):	
Interest income.....	1,488,250
Interest expense.....	(866,799)

Net interest income.....

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