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GENOME THERAPEUTICS CORP

Form 10-K

March 31, 2003

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SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

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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, 2002

OR

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

Commission file number: 0-10824

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GENOME THERAPEUTICS CORP.  
(Exact name of registrant as specified in its charter)

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Massachusetts	04-2297484
(State or other	(IRS employer
jurisdiction	identification number)
of incorporation or	
organization)	

100 Beaver Street,	02453
Waltham, Massachusetts	
(Address of principal	(Zip Code)
executive offices)	

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

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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

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Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such

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filing requirements for the past 90 days. Yes [X] 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 [ ]

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes [ ] No [X]

The aggregate market value of the voting and non-voting common equity held by non-affiliates as of June 28, 2002, the last business day of the registrant's most recently completed second fiscal quarter, was approximately \$53,333,000.

The number of shares outstanding of the registrant's common stock as of March 25, 2003 was 23,635,460.

Documents Incorporated By Reference. Portions of the registrant's proxy statement for use at its Annual Meeting to be held on May 9, 2003 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, development and commercialization of pharmaceutical and diagnostic products. Our strategic goal is to directly participate in the commercialization of products that are used primarily in hospitals. For diseases treated by larger physician audiences, we seek to discover, develop and commercialize products through alliances with major pharmaceutical companies.

We have nine established product development programs. We are managing the development and commercialization of our lead product candidate, Ramoplanin, in the United States and Canada. This product is in a Phase III clinical trial for the prevention of bloodstream infections caused by vancomycin-resistant enterococci (VRE) and a Phase II trial for the treatment of patients with Clostridium difficile-associated diarrhea (CDAD). We have seven product discovery and development alliances with pharmaceutical companies including Amgen, AstraZeneca, bioMerieux, Schering-Plough and Wyeth. In addition, we have a portfolio of internal drug discovery programs. During 2002, we also maintained an active service business, GenomeVision/TM/ Services, providing drug discovery services to pharmaceutical and biotechnology companies and to the National Human Genome Research Institute. As part of our continued evolution into a biopharmaceutical company, this business unit was divested in March 2003.

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

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

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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 \$22 billion in 2002.

We seek to supplement our drug discovery efforts with an active in-licensing program. Our in-licensing efforts are focused on products in preclinical and/or clinical development that will complement our internal drug discovery efforts for infectious diseases as well as our strategic focus on the hospital target market. In October 2001, we in-licensed the compound Ramoplanin, a novel glycolipodepsipeptide antibiotic produced by fermentation of the bacteria *Actinoplanes*, with activity against Gram-positive aerobic and anaerobic microorganisms. We are developing this antibiotic for the prevention of bloodstream infections caused by VRE and the treatment of *Clostridium difficile*-associated diarrhea (CDAD). We have invested to build an experienced clinical development and regulatory team that is overseeing the clinical development of Ramoplanin. We have also built a commercial team to develop and implement the marketing planning effort for this product.

We have long been a leader in the use of genomics to discover new drugs for the treatment of bacterial and fungal infections. 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 two ongoing anti-infective discovery and development collaborations with Schering-Plough. The first is focused on new treatments for drug-resistant bacterial infections, including those caused by *Staphylococcus aureus*, and the second is focused on identifying novel antifungals. We have partnered with AstraZeneca to develop treatments for ulcers caused by *Helicobacter pylori* (*H. pylori*) and with bioMerieux to develop diagnostics for bacterial infections.

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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 three alliances with pharmaceutical companies: Schering-Plough for the discovery of new treatments for asthma; Wyeth for the prevention or treatment of osteoporosis; and Amgen for the prevention and treatment of bone diseases, including osteoporosis. We also continue to invest in the development of new therapies for the treatment of other chronic human diseases, including central nervous system disorders.

Our internal discovery efforts are focused on bacterial and fungal infections. During the last two years, we have built a high-throughput screening capability and a diverse compound library of approximately 130,000 compounds derived from commercial sources. We have invested in our in vivo, pre-clinical capabilities and have commenced in vivo testing on several compounds. We have also formed joint ventures and collaborations with other biotechnology companies to discover and develop new broad-spectrum antibiotics. While we will seek to partner some of these programs with larger companies, we may also develop and commercialize some of these discoveries ourselves for niche opportunities, such as hospital-acquired infections or infections in immunocompromised patients.

### Biopharmaceutical and Diagnostic Programs

We have nine ongoing product development programs. Our lead product

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candidate, Ramoplanin, is in a Phase III clinical trial for the prevention of bloodstream infections caused by VRE and a Phase II clinical trial for the treatment of Clostridium difficile-associated diarrhea (CDAD). We have seven alliances with pharmaceutical companies including Amgen, AstraZeneca, bioMerieux, Schering-Plough and Wyeth. In addition to these seven alliances, we have a number of collaborators and a portfolio of 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 human gastrointestinal (GI) 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 rate of over 30%.

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 2000, more than 26% of intensive care unit enterococci infections were caused by VRE, a 93% 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 are not only resistant to vancomycin, but also to other common antibiotics. This resistance provides VRE with a selective advantage over other enterococcal isolates in the gut and enables resistant pathogens to easily colonize the human 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 diseases community has been placed on infection control practices within the hospital to prevent VRE infections. Infection control has focused on

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screening to identify colonized patients and the use of barrier methods to avoid the spread of the bacteria to other patients. Typically, these measures 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 decolonize the gut in an attempt to prevent VRE bloodstream infections. However, attempts to prevent VRE bloodstream infections by decolonization have been unsuccessful. Bacitracin to date 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 sufficient levels in the gut to suppress VRE effectively.

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Clostridium difficile-associated diarrhea (CDAD), a serious form of colitis caused by toxins produced by the Gram-positive bacteria Clostridium difficile (C. difficile), is the most common form of antibiotic-associated diarrhea in the hospital. One study has demonstrated that as many as 20% of hospital patients are colonized with C. difficile either prior to or during admission. Because it is a spore-forming bacterium, C. difficile is readily spread from person to person, especially in the hospital and nursing home environment. Under certain conditions, such as extended antibiotic therapy and gastrointestinal surgery, C. difficile can colonize the gut and release toxins, leading to bowel inflammation and severe diarrhea. Serious cases can occur and involve the development of fulminant colitis (severe inflammation of the colon); such occurrences can be life threatening, especially in elderly or immunocompromised populations.

Over 400,000 patients are treated in U.S. hospitals each year for CDAD. CDAD is associated with an average increase of length of stay in the hospital of 3.6 days and an average increase in hospital costs of over \$3,600 per patient. It is estimated that the annual increase in hospital costs attributable to CDAD exceeds \$1 billion.

Current therapies for the treatment of CDAD include oral metronidazole and oral vancomycin. Both of these agents are associated with a 15-20% relapse rate. The use of oral vancomycin has been associated with the selection of vancomycin-resistant organisms, including VRE. The use of oral metronidazole has been associated with increased density of VRE in the gastrointestinal tracts of treated patients. Resistance has been reported for both drugs. Finally, both drugs are used extensively for the treatment of systemic infections outside of the gastrointestinal tract.

In October 2001, we in-licensed Ramoplanin from Biosearch Italia S.p.A (which merged with Versicor Inc. in March 2003). Subsequently, Versicor changed its name to Vicuron Pharmaceuticals Inc. (Vicuron). Ramoplanin is a novel glycolipodepsipeptide antibiotic produced by fermentation of the bacteria Actinoplanes, with activity against Gram-positive aerobic and anaerobic microorganisms. In preclinical studies, Ramoplanin has been shown to be bactericidal against most Gram-positive species, including methicillin-resistant staphylococci, VRE and C. difficile. 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: Ramoplanin Profile--below) that may make it a particularly attractive compound for killing bacteria in the GI tract. This may make the product a useful drug in the treatment of certain infections (such as 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. Finally, Ramoplanin may show value in preventing patient-to-patient transmission of Gram-positive pathogens in the hospital setting.

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Table : Ramoplanin Profile

Characteristic	Potential Advantage
Novel class of antibiotic	No observed cross-resistance with other antibiotics No observed resistance

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Orally administered, but not absorbed into bloodstream	Concentrates and exerts its killing effects in the GI tract
Bactericidal	Rapid killing effect
	Less likely to develop resistance
	Potential value to prevent patient-to-patient transmission of pathogens
Gram Positive Spectrum	Low potency against Gram-negative anaerobes
	Less likely to result in overgrowth of other opportunistic organisms
	Potential value vs. <i>C. difficile</i>

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 GI tract, while all of the placebo patients had detectable VRE ( $p=0.01$ ). Ramoplanin has been granted Fast Track status 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 Ramoplanin reduces the incidence of VRE bloodstream infections in cancer patients carrying VRE bacteria in their intestines. Approximately half of the planned 950 patients have been enrolled in the study at more than 40 clinical trial sites in the U.S. and more than 50% of the projected 65 events (bloodstream infections caused by VRE) required for completion have been recorded. We have stated our goal of filing a New Drug Application in 2004. Enrollment in this study remains challenging due, in part, to many potential patients being excluded from the study because of their participation in other clinical trials to treat their underlying malignancies. We continue discussions with the FDA to introduce modifications to our Phase III trial, aimed at accelerating completion of the trial and increasing the probability of meeting our 2004 filing goal.

Shortly after the close of 2002, we began a Phase II trial to assess the safety and efficacy of Ramoplanin to treat CDAD. The protocol calls for an 87-person, open-label, multi-center trial comparing two doses of Ramoplanin (200 mg and 400 mg twice daily) to vancomycin (which requires a dose of 125 mg four times daily for the treatment of CDAD). Both agents will be administered for ten days, during which data on Ramoplanin will be collected to measure safety and efficacy. The results of the Phase II trial will guide the design of a Phase III investigation of Ramoplanin for the treatment of CDAD. Ramoplanin has demonstrated in vitro activity against *C. difficile*, including strains resistant to metronidazole and vancomycin.

The CDAD Phase II trial will use a newly developed capsule formulation of Ramoplanin. At the end of 2002, we announced the completion of a clinical study comparing the microbiological activity and the pharmacokinetic profile of the capsule and sachet (powder for reconstitution) formulations. Analysis of the data confirmed Ramoplanin's ability to suppress enterococci in the GI tract. Further, both formulations were equally active microbiologically and there was no evidence of systemic absorption with either formulation. Developing this capsule formulation is an important step toward readying the product for commercialization, as a capsule is expected to be the formulation preferred by most patients.

Our license agreement with Vicuron provides us with exclusive rights to develop and market oral Ramoplanin in the U.S. and Canada. Vicuron will provide

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the bulk material for the manufacture of the product. Under the terms of the agreement, we paid Vicuron initial consideration of \$2 million. We will also 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 Vicuron, we will fund the completion of clinical trials and pay a royalty to Vicuron on product sales. The combined total of bulk product purchases and royalties is expected to be 26% of our net product sales.

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We have established a joint committee with Vicuron 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 our success in product discovery and development. The following table summarizes our existing product discovery and development partnerships:

Bacterial and Fungal Infections Alliances			Proceeds Received Pot
Alliance Focus	Partner ( Date of Agreement)	Status of Alliance	as of December 31, 2002
Ulcers	AstraZeneca (September 1995)	Contract research program completed; Program transferred to AstraZeneca; Currently in lead optimization.	\$13.7 million
Drug-Resistant Bacterial Infections	Schering-Plough (December 1995)	Contract research program completed; Validated targets and screening assays transferred to Schering-Plough; Currently in high-throughput screening.	\$21.5 million
Fungal Infections	Schering-Plough (September 1997)	Contract research program 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(TM) Database delivered; Identification of gene markers ongoing.	\$4.4 million

Human Disease Alliances			Proceeds Received as of December 31, Potential Pro
Alliance Focus	Partner (Date of Agreement)	Status of Alliance	2002 Excluding Roy

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Osteoporosis	Wyeth (December 1999)	Identified specific gene mutation that leads to increased bone mass; Contract research extended through December 2003; Currently in high-throughput screening.	\$9.2 million	\$119.0 mill
Asthma	Schering-Plough (December 1996)	Two genes discovered; Transferred to Schering-Plough in January 2003; Currently in high-throughput screening.	\$42.4 million	\$81.0 mill
Bone Diseases	Amgen** (December 2002)	Gene target identification underway.	\$0	\$67.0 mill

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\* Assumes receipt or payment of all license fees, funded research and contingent payments for achieving milestones, after extensions and/or reallocations; excludes potential royalties.

\*\* If all milestones are met in our alliance with Amgen, total payments to us will approximate \$67.0 million, excluding royalties, if a single product is developed, and a maximum of \$104.0 million, excluding royalties, if more than one product is developed under the agreement.

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### 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 was \$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 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 franchise, which includes Nexium(R) and Prilosec(R), generated worldwide sales of \$6.2 billion in 2001. As of December 31, 2002, we had received payments of \$13.7 million under this alliance and have rights to receive, based on attainment of milestones, an additional \$9.6 million of payments in addition to potential royalties. In August 1999, we completed our research obligations under this alliance and turned over validated drug targets and assays to AstraZeneca for pre-clinical testing. AstraZeneca announced in 2002 that it had begun a lead optimization program on a lead identified through the high-throughput screening program conducted using one of these targets. As of March 31, 2003, Astra's exclusive access rights to our H. pylori genomic sequence technology will terminate and we will be able to enter into alliances with other partners to develop drugs, vaccines and diagnostic products effective against peptic ulcers or any other disease caused by H. pylori.

#### Drug-Resistant Bacterial Infections



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The pathogen *Staphylococcus 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 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 infections caused by *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, 2002, we had received payments of \$21.5 million under this alliance and have rights to receive, based on attainment of milestones, an additional \$24.0 million of payments as well as potential royalties. As of December 31, 2001, we had completed our research obligations under this alliance and had turned over validated drug targets and assays to Schering-Plough for high-throughput screening.

### 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 \$4.3 billion in 2002, with non-prescription

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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 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, 2002, 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. In early 2002, we completed our research obligations under this alliance and 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 14 million people worldwide die of an infectious disease each year, with many of those infections acquired in hospitals. There has been a global resurgence of infectious

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diseases, including the identification of new pathogens, the re-emergence of old infectious agents and the rapid spread of resistance to anti-infective agents. Rapidly identifying the specific microorganisms involved in a 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 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 provided by bioMerieux approximates \$5.2 million for the four-year term of this agreement. As of December 31, 2002, we had received payments of \$4.4 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 were \$17.0 billion in 2001. 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 to the development of diagnostic tests.

In December 1999, we formed an alliance with Wyeth to develop drugs to treat osteoporosis based on our genetic research. Wyeth 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, 2002, we had received payments of \$9.2 million under this alliance and have rights to receive, subject to the achievement of milestones, an additional \$109.8 million in 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. In

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the January 2002 issue of the American Journal of Human Genetics, we reported the identification of a specific gene mutation in the LRP5 gene that leads to increased bone mass. Also in 2002, this program entered high-throughput screening for drug candidates. Recently, the sponsored research phase of this alliance was extended through December 31, 2003.

#### Asthma

Asthma affects over 155 million people worldwide according to the World Health Organization and the incidence of asthma appears to be rising

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dramatically. In the United States, the incidence of asthma has doubled over the past two decades and affects approximately 4% to 10% of the United States population. The annual direct and indirect costs associated with treating the disease exceed \$15.0 billion. 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 is a leader in the field of allergy and respiratory care products, with products such as Afrin(R) nasal spray, a leading product in the branded nasal spray market, and Clarinex(R) and the Claritin(R) line of antihistamines, which generated \$2.0 billion in sales in 2002. As of December 31, 2002, we had received payments of \$42.4 million under this alliance and have rights to receive, based on attainment of milestones, an additional \$38.6 million of payments as well as potential royalties. During the past two years, we used our proprietary genomics tools, bioinformatics and high-throughput sequencing to discover two genes associated with asthma. As of December 31, 2002, we had completed our research obligations under this alliance. The two genes discovered have been transferred to Schering-Plough for further drug discovery efforts. In 2002 this program advanced into high-throughput screening for drug candidates and the first gene discovery was published in the peer-reviewed journal, Nature.

### Bone Diseases

On January 2, 2003, we announced an agreement with Amgen Inc. for the identification and development of novel therapeutic agents for bone diseases, including osteoporosis. Both companies will participate in collaborative research efforts to discover one or more drug candidates suitable for development. The companies may, as part of the research activities, use genetic information, developed by us based on research conducted at the Creighton University Osteoporosis Research Center, which has been exclusively licensed to Amgen.

As part of the agreement, we will receive from Amgen an upfront cash payment, sponsored research funding, and potentially additional milestones and other downstream consideration depending on the success of the discovery, development and commercialization activities. Amgen will be responsible for development and commercialization of any products.

Contingent upon the success of the discovery, development and commercialization activities, Amgen may also purchase shares of our common stock. Amgen's equity ownership in us will be limited to no more than 4.99% of our outstanding shares. If all milestones are met, total payments to us will approximate \$67.0 million, excluding royalties, if a single product is developed, and a maximum of \$104.0 million, excluding royalties, if more than one product is developed under the agreement. Of the total potential payments for one product, approximately \$59 million represents research payments, milestone payments and a license fee, and \$8.0 million represents an equity investment in us by Amgen. We recognized approximately \$42,000 in revenue during the year ended December 31, 2002, which consisted of amortization of an up-front license fee.

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

Internal Drug Discovery

Bacterial and Fungal Infections

Our internal pre-clinical anti-infectives efforts are directed at discovering new antibiotics active against novel antimicrobial targets. We accomplish this through both our internal investment and through joint ventures with other biotechnology companies. We began this effort two years ago focusing on our family of validated microbial targets. Using our proprietary functional genomics technology, our scientists have been able to discover bacterial and fungal genes that are essential for the survival of pathogenic organisms. Our gene discovery approach has generated 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. We have built a compound library of over 130,000 compounds and generated more than 3 million screening data points on a dozen of our genomic targets. From our screening efforts, we have established a growing portfolio of hits and leads.

We have formed two joint ventures focused on discovering new broad-spectrum antibacterials: one with ArQule, beginning in 2000; and one with MerLion Pharmaceuticals initiated at the beginning of 2003.

In October 2000, we formed a joint venture with ArQule, Inc. The joint venture, which replaced an earlier 1998 collaboration agreement between the companies, included commitment of shared, dedicated scientific and technical resources from both companies and joint ownership rights to all lead compounds and commercial outcomes that result from this effort. The joint venture focused on the discovery and development of novel, small molecule, broad-spectrum antibacterials. In July 2002, the companies announced they had nominated two anti-infective lead compound series for optimization arising out of the collaboration. By screening chemical compounds against validated microbial genomic targets that we identified and by performing microbiological, biochemical and hit-to-lead chemical analyses, the companies were able to identify these novel small molecule compound series. At that time, the companies also announced an agreement to restructure their joint venture arrangement. Under the restructuring, Genome Therapeutics will take full operational and financial responsibility for advancing these leads through optimization and clinical development, thus ending ArQule's involvement in this joint venture.

We recently initiated a second drug discovery joint venture, this one with MerLion Pharmaceuticals, aimed at identifying natural products with potential utility as anti-infective drugs. This effort will focus on leveraging our validated antibacterial drug targets against MerLion's extensive natural product libraries to select compounds for future clinical development, including those appropriate for Investigational New Drug (IND) status. We will share all costs and expenses of the early-stage drug discovery research with MerLion. We will provide MerLion with screening assays on target proteins essential for the survival of many common pathogens. MerLion will screen the targets against its vast natural product libraries to isolate and identify novel chemical entities with an inhibitory effect on the target proteins. We will profile active compounds for their in vitro and in vivo antibacterial properties to identify novel antibacterial lead series. A joint research committee, comprised of members from both companies, will monitor and direct the course of the research. Both companies retain rights for lead optimization, clinical development and commercialization of lead candidates identified during

the collaboration.

We initiated a collaboration with InterLink Biotechnologies for accessing their libraries of natural products for cell-based screening. Having access to InterLink's and MerLion's natural product libraries is critical for expanding our broad-spectrum anti-infective drug development program, as we seek to increase the number of clinical candidates in our pipeline.

In June, we commenced a new collaboration with F2G Limited to discover novel antifungal drugs. In this effort, F2G is using our in-house compound library and F2G's antifungal whole-cell assay screening capabilities

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to identify specific compounds with potent activity against medically important fungal pathogens. The combination of our in-house compound library with F2G's high-throughput whole-cell assay screening expertise supports our efforts to advance the next generation of novel antifungals, either through internal efforts or with a development partner.

Shortly after the close of 2002, we entered into an agreement with PanTherix to support our lead optimization activities. PanTherix will apply its protein structure determination expertise to provide structural information on our drug targets and leads, providing important information on drug-protein interactions and accelerating the development of antibacterial drug candidates. By using PanTherix's x-ray technology, we are gaining information that we expect will support the progress of our lead optimization projects.

As a result of our internal drug discovery efforts, we have identified two novel lead chemical series, GTC-162 and GTC-637 analogs, and are entering the lead optimization phase. These two lead series are aimed at novel, broad-spectrum targets and have the potential to be new classes of antibacterials. Behind these lead compounds, we have identified hit series on six additional antimicrobial screens. As these compound series progress, we may enter into alliances with other companies to engage in their development, commercialization and marketing.

#### Chronic Human Diseases

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 and our osteoporosis alliance have advanced into high throughput screening for drug candidates.

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

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expertise, the clinical development capabilities and the sales and marketing infrastructure required to discover and develop new drugs in these areas.

### GenomeVision(TM) Services

As part of our continued evolution into a focused biopharmaceutical company, in March 2003, we sold our GenomeVision(TM) Services business to privately held Agencourt Bioscience Corporation. As part of the agreement, we transferred our sequencing operations, including certain equipment and personnel to Agencourt. We will receive a percentage of revenues from commercial and government customers, transferred to Agencourt, for a period of two years, as well as shares of Agencourt common stock. We retain rights to our PathoGenome(TM) Database product, including all associated intellectual property, subscriptions and royalty rights on products developed by subscribers. Furthermore, we retain the capabilities necessary to satisfy the research needs of our existing product-focused alliances, as well as potential new alliances. Through this divestiture, we eliminated approximately 60 full-time positions.

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. We have been scheduled to receive funding from the NHGRI of up

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to \$17.4 million through February 2003, of which all funds have been appropriated. This grant is intended to be transferred to Agencourt and subject to the terms of the divestiture agreement.

In October 1999, the U.S. Government named us as one of ten initial centers in the Mouse Genome Sequencing Network. 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 our 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. This grant is intended to be transferred to Agencourt and subject to the terms of the divestiture agreement.

### PathoGenome(TM) Database

In 1997, we introduced to the market the PathoGenome(TM) 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(TM) 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 designed the PathoGenome(TM) Database to be accessed at the client site using our proprietary bioinformatics software. The PathoGenome(TM) Database enables researchers to search for new genes among multiple pathogens and cross-reference genomic information for the development of new anti-infective products. In 2001, we entered into an agreement with EraGen Biosciences, under which they are responsible for the marketing, distribution and maintenance of this product, while we retain our rights to use it and receive a percentage of subscription fees and royalties from subscriber discoveries.

### Our Technology

We have created an integrated platform of drug discovery technologies that

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include target identification and validation, single nucleotide polymorphism (SNP) discovery and typing, bioinformatics, assay development, high-throughput screening and compound profiling capabilities.

### Internal Drug Discovery Technologies

We have internal capabilities to identify and screen compounds against validated drug targets. Our screening technologies allow for the high-throughput use of biochemical and cell-based screening assays. From these screens, we have used our bioinformatics expertise to build a diverse compound library of over 130,000 compounds from which we can produce profiles based on the compound's "drug-like" properties. Since 2001, we have screened our libraries against multiple targets generating over 3 million data points and advanced two internally-derived compounds series into lead optimization.

### Gene Target Identification Technologies

We possess the capabilities to perform genetic sequencing, with a focus on gene mutation and SNP identification. Using our advanced genotyping techniques for sequencing and finishing, we identify specific gene mutations and SNPs with relevance to chronic human diseases. Through this process, robust raw data is produced and subsequently organized, managed, and analyzed by the bioinformatics team using computers, software, and databases. With this approach, we have identified three gene mutations; one linked to high bone mass, and two linked to asthma susceptibility.

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### 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 we have not characterized the biological function of a gene or gene fragment at the time of filing a patent application, 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. We have over 15 pending U.S. patent applications and one issued patent on genes and protein sequences of pathogenic organisms. Three of the pending patent applications are allowed by the U.S. PTO and are expected to issue in the near future.

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. PTO issued guidelines limiting the number of nucleic acid sequences that can be covered in a single patent application.

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In addition, the U.S. courts continue to redefine and narrow the enforceable scope of claims to genes, gene fragments, SNPs, and proteins. In 2000, 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 U.S. PTO 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 have also filed patent applications on pharmaceutical compositions and corresponding medical uses of these compositions resulting from our clinical trials, and new chemical entities resulting from our internal research programs. We file foreign counterparts to these U.S. applications within the appropriate timeframes. These patent applications seek to protect our pharmaceutical compositions and other products as well as the uses and processes related to these pharmaceutical compositions and products.

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 submit sequencing data resulting from the research to public databases within 24 hours of the date on which we generate such data and materials. The government 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.

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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,



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challenged, opposed, narrowed, invalidated or circumvented.

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 therefore 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.

### Competition

The biopharmaceutical industry generally, and our 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.

Many of our competitors have greater research and product development capabilities and financial, scientific, marketing and human resources than we do, and some competitors' drug discovery and clinical development programs are more advanced than our programs. Therefore, our competitors may succeed in discovering 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. Potential products based on genes that we have identified or may identify in our discovery efforts may face competition both from companies developing gene-based products and from companies developing antibiotics and other forms of diagnosis or treatment for the particular diseases.

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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,
- . our ability to obtain regulatory approvals for our product candidates in a cost efficient and timely manner,

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- . 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 internally or in-license product candidates for clinical development, and
- . our ability to secure sufficient capital resources to fund our research and clinical development operations.

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 companies seeking to discover human disease genes is also increasing for access to unique data from related individuals that are employed to identify those genes. 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. 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 Food and Drug Administration (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 U.S. 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, and
- . 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 premarket approval involves the following process, which may be costly and time-consuming:

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

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, Vicuron (which was formed through the merger of Biosearch Italia SpA. and Versicor Inc. in March 2003) 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 also plan to 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 FDA's 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.

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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 that a pharmaceutical marketing partner would provide. We currently do not have the resources to market Ramoplanin by ourselves, but fully expect to assemble a sales and marketing organization at the appropriate time.

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### Human Resources

As of December 31, 2002, we had 152 full-time equivalent employees, with 122 of these employees engaged in research and development activities and 30 of them conducted general and administrative functions. Twenty-seven of our employees held Ph.D. degrees and 34 more held other advanced degrees. Following the divestiture of our GenomeVision(TM) Services business unit in February 2003, we had 95 employees, of which 68 of these employees engaged in research and development activities and 27 of them conducted general and administrative functions. Currently, 20 of our employees hold Ph.D. degrees and 20 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.

### Item 2. Properties

#### 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 2002, we incurred aggregate rental costs, excluding maintenance and utilities, for our facility of approximately \$1,020,000.

### 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 2002 and 2001 as furnished by the National Association of Securities Dealers Quotation System.

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	2002		2001	
	High	Low	High	Low
First Quarter.	\$7.200	\$4.930	\$11.690	\$4.750
Second Quarter	5.810	2.000	16.900	4.781
Third Quarter.	2.390	1.250	15.450	4.010
Fourth Quarter	2.480	1.000	8.390	5.450

As of March 26, 2003, there were approximately 1,036 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 general business conditions.

Item 6. Selected Consolidated Financial Data

	For the Year Ended December 31,				
	1998	1999	2000	2001	2002
Revenues:					
Biopharmaceutical.....	\$ 18,135,038	\$ 18,162,056	\$ 11,851,091	\$ 18,438,286	\$ 7,715
GenomeVision(TM) Services...	3,913,376	6,665,529	13,594,143	17,302,239	15,270
Total revenues.....	22,048,414	24,827,585	25,445,234	35,740,525	22,986
Net loss.....	(12,967,676)	(3,940,075)	(5,846,839)	(10,090,302)	(34,017)
Net loss per common share.....	(0.71)	(0.21)	(0.27)	(0.45)	(
Weighted average common shares outstanding.....	18,289,644	18,627,045	21,376,685	22,572,427	22,920

	As of December 31,				
	1998	1999	2000	2001	2002
Cash and cash equivalents, restricted cash, warrant and long and short-term marketable securities.....	\$30,816,859	\$26,778,026	\$73,009,887	\$67,341,249	\$50,8
Working capital.....	19,749,608	19,447,189	51,601,069	44,156,478	36,5
Total assets.....	48,920,973	45,443,236	90,251,004	82,739,598	65,8
Shareholders' equity.....	27,557,237	28,846,957	72,687,452	66,731,938	35,4

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

Forward-Looking Statements

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Certain information contained in this report should be considered "forward-looking statements" as defined by the Private Securities Litigation Reform Act of 1995. These statements represent, among other things, the expectations, beliefs, plans and objectives of management and/or assumptions underlying or judgments concerning and future financial performance and other matters discussed in this document. The words "may,"

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"will," "should," "plan," "believe," "estimate," "intend," "anticipate," "project," and "expect" and similar expressions are intended to identify forward-looking statements. All forward-looking statements involve certain risks, estimates, assumptions, and uncertainties with respect to future revenues, cash flows, expenses and the cost of capital, among other things.

Some of the important risk factors that could cause our actual results to differ materially from those expressed in our forward-looking statements include, but are not limited to:

- . risks related to our lead product candidate, Ramoplanin, such as (i) our inability to obtain regulatory approval to commercialize Ramoplanin due to negative, inconclusive or insufficient clinical data and (ii) delays in the progress of our clinical trials for Ramoplanin, and increased cost, due to the pace of enrollment of patients in the trials or fluctuations in the infection rate of enrolled patients;
- . our inability or the inability of our alliance partners to successfully develop and obtain regulatory approval for products based on our genomics information;
- . our history of operating losses and our need to raise future capital to support our product development and research initiatives;
- . intensified competition from pharmaceutical or biotechnology companies that may have greater resources and more experience than us;
- . our inability to obtain or enforce our intellectual property rights; and
- . our dependence on key personnel.

In addition to the risk factors set forth above, you should consider the risks set forth in Exhibit 99.1 to this Annual Report, the "Business" section of this Annual Report and elsewhere in our filings with the Securities and Exchange Commission. We undertake no obligation to revise the forward-looking statements included in this Annual Report to reflect any future events or circumstances.

### Overview

We are a biopharmaceutical company focused on the discovery, development and commercialization of pharmaceutical and diagnostic products. Our strategic goal is to directly participate in the commercialization of products that are used primarily in hospitals. For diseases treated by larger physician audiences, we seek to discover, develop and commercialize products through alliances with major pharmaceutical companies.

We have nine established product development programs. We are managing the development and commercialization of our lead product candidate, Ramoplanin, in the United States and Canada. This product is in a Phase III clinical trial for the prevention of bloodstream infections caused by vancomycin-resistant

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enterococci (VRE) and a Phase II trial for the treatment of patients with Clostridium difficile-associated diarrhea (CDAD). We have seven product discovery and development alliances with pharmaceutical companies including Amgen, AstraZeneca, bioMerieux, Schering-Plough and Wyeth. In addition, we have a portfolio of internal drug discovery programs. During 2002, we also maintained an active service business, GenomeVision/TM/ Services, providing drug discovery services to pharmaceutical and biotechnology companies and to the National Human Genome Research Institute. As part of the our continued evolution into a biopharmaceutical company, this business unit was divested in March 2003.

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

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

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In October 2001, we acquired an exclusive license in the United States and Canada for a novel antibiotic, Ramoplanin, from Biosearch Italia S.p.A, which merged with Versicor Inc. (Versicor) in March 2003. Subsequently, Versicor changed its name to Vicuron Pharmaceuticals Inc. (Vicuron). We have assumed responsibility for the product development in the United States of Ramoplanin, currently in a Phase III clinical trial for the prevention of bloodstream infections caused by vancomycin-resistant enterococci (VRE), as well as a Phase II clinical trial to assess the safety and efficacy of Ramoplanin to treat Clostridium difficile-associated diarrhea (CDAD). Our license agreement with Vicuron provides us with exclusive rights to develop and market oral Ramoplanin in the United States and Canada. Vicuron will retain all other rights to market and sell Ramoplanin. In addition, we are obligated to purchase bulk material from Vicuron, fund the completion of clinical trials and pay a royalty on product sales. Upon commercialization the combined total of bulk product purchases and royalties is expected to be approximately 26% of our net product sales.

Our primary sources of revenue are from alliance agreements with pharmaceutical company partners. Currently, we have seven major product discovery alliances, and we currently receive contract research funding from three of these alliances. In August 1995, we entered into an alliance with AstraZeneca to develop pharmaceutical, vaccine and diagnostic products effective against gastrointestinal infections or any other disease caused by Helicobacter pylori (H. pylori). In August 1999, the contract research under the alliance concluded and the program transitioned into AstraZeneca's pipeline. We are entitled to receive additional milestone payments and royalties based upon the development by AstraZeneca of any products from the research alliance. In December 1995, we entered into an alliance with Schering-Plough. Under this alliance, Schering-Plough can use our Staphylococcus aureus (Staph. aureus) genomic database to identify new gene targets for the development of novel antibiotics. In March 2002, we had completed our research obligations under this alliance and had turned over validated drug targets and assays to Schering-Plough for high-throughput screening. In December 1996, we entered into our second research alliance with Schering-Plough to identify genes and associated proteins that Schering-Plough can utilize to develop new pharmaceuticals for treating asthma. In December 2002, we had completed our research obligations under this alliance and the research program has advanced into high-throughput screening at Schering-Plough to identify drug candidates. In September 1997, we established our third research alliance with Schering-Plough for the development of new

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pharmaceutical products to treat fungal infections. In March 2002, we had completed our research obligations under this alliance and had turned over validated drug targets and assays to Schering-Plough for high-throughput screening. In September 1999, we entered into a strategic alliance with bioMerieux to develop, manufacture and sell in vitro pathogen diagnostic products for human clinical and industrial applications. As part of the strategic alliance, bioMerieux purchased a subscription to our PathoGenome(TM) Database and made an equity investment in the Company. In December 1999, we entered into a strategic alliance with Wyeth to develop drugs based on our genetic research to treat osteoporosis. In December 2002, we entered into a strategic alliance with Amgen, Inc. to identify and develop novel therapeutic agents for bone diseases, including osteoporosis.

In 2002 and past fiscal years, we have also received revenues from our GenomeVision(TM) Services business from selling, as a contract service business, high quality genomic sequencing information to our customers. As part of our continued evolution into a focused biopharmaceutical company, on March 14, 2003, we completed the sale of our GenomeVision(TM) Services business to privately held Agencourt Bioscience Corporation. As part of the agreement, we transferred our sequencing operations, including certain equipment and personnel to Agencourt. We will receive a percentage of revenues from commercial and government customers, transferred to Agencourt, for a period of two years from the date of sale, as well as shares of Agencourt common stock. We retain rights to our PathoGenome(TM) Database product, including all associated intellectual property, subscriptions and royalty rights on products developed by subscribers. Furthermore, we retain the capabilities necessary to satisfy the research needs of our existing product-focused alliances, as well as potential new alliances. We do not expect the sale of the GenomeVision(TM) Services business to have a significant impact on our net loss during the next two years, as a result of reductions in costs associated with this sale and our rights to receive royalties on gene sequencing revenue earned by Agencourt that is related to the transferred business for a period of two years from the date of sale.

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In connection with the sale of its GenomeVision(TM) Services business, we determined that certain equipment related to this segment will no longer be used and will be abandoned subsequent to the sale. As a result, we revised the estimated useful lives of this equipment and recorded additional depreciation expense of \$669,000 during the fourth quarter of 2002. We also evaluated and wrote down our excess inventory of disposables related to the GenomeVision(TM) Services business by \$312,000 during the fourth quarter of 2002. Additionally, through this divestiture, we eliminated approximately 60 full-time positions, of which approximately 49 employees were not offered employment with Agencourt. We will record and pay severance costs of approximately \$636,000 during the first quarter of 2003 related to these employees.

In May 1997, we introduced our PathoGenome(TM) 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, 2002, we had seven subscribers. In 2001, we entered into an agreement with EraGen Biosciences, under which they are responsible for the marketing, distribution and maintenance of this product, while we retain our rights to use it and receive a percentage of subscription fees and royalties from subscriber discoveries. Under our agreements, the subscribers receive non-exclusive access to information relating to microbial organisms in our PathoGenome(TM) 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. Our revenues relating to subscription fees declined in 2002, and we



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expect to see a further revenue decline in subscription fees over the next year as subscribers complete their data mining of the PathoGenome/TM/ Database.

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. In July 1999, we were named as one of the nationally funded DNA sequencing centers of the international Human Genome Project. We received funding from the National Human Genome Research Institute (NHGRI) of \$18.4 million through June 2003, of which all funds have been appropriated and \$17.4 million has been received through December 31, 2002. As part of the sale of GenomeVision/TM/ Services to Agencourt, this program, as well as follow-on work associated with this project, is expected to be transferred to Agencourt and we expect to receive royalty payments on revenues earned by Agencourt for a period of two years from the date of sale. In October 1999, the NHGRI named us as a pilot center to the Mouse (Rat) Genome Sequencing Network. We received \$14.8 million in funding through February 2003 with respect to this agreement, of which all funds have been appropriated and \$14.1 million had been received through December 31, 2002. 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, were redirected to the Rat Genome Sequencing Program. Any follow-on work associated with this grant is expected to be transferred to Agencourt and be subject to the terms of the purchase agreement with Agencourt.

We receive payments under our biopharmaceutical business from our product discovery alliances based on license fees, contract research and milestone payments during the term of the alliance. We anticipate that our alliances will result in the discovery and commercialization of novel pharmaceutical, vaccine and diagnostic products. In order for a product to be commercialized based on our research, it will be necessary for our product discovery partner to conduct preclinical tests and clinical trials, obtain regulatory clearances, manufacture, sell, and distribute the product. Accordingly, we do not expect to receive royalties based upon product revenues for many years, if at all.

We have incurred significant operating losses since our inception. As of December 31, 2002, we had an accumulated deficit of approximately \$125.8 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.

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### New Accounting Pronouncements

In August 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Statement No. 144 (SFAS No. 144), "Accounting for the Impairment or Disposal of Long-Lived Assets," which addresses financial accounting and reporting for the impairment or disposal of long-lived assets and supercedes SFAS No. 121, "Accounting for Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of" and the accounting and reporting provisions of APB Opinion No. 30, "Reporting the Results of Operations," for a disposal of a segment of a business. SFAS No. 144 is effective for fiscal years beginning after December 15, 2001, with transition provisions for assets "held

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for sale" that were initially recorded under previous models (APB No. 30 or SFAS No. 121) and do not meet the new "held for sale" criteria. The Company adopted SFAS No. 144 in the first quarter of 2002.

In May 2002, the FASB issued Statement of Financial Accounting Standard No. 145 (SFAS 145), "Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections". Among other things, SFAS 145 rescinds Statement of Financial Accounting Standards No. 4 (SFAS 4), "Reporting Gains and Losses from Extinguishment of Debt" and eliminates the requirement that gains and losses from the extinguishment of debt be classified as an extraordinary item, net of related income tax effects, unless the criteria in Accounting Principles Board 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" are met. Adoption of this statement is generally required in fiscal years beginning after May 15, 2002. We do not expect the adoption of this statement to have a material impact on our consolidated financial statements.

In June 2002, the FASB issued Statement of Financial Accounting Standard No. 146 (SFAS 146), "Accounting for Costs Associated With Exit or Disposal Activities". SFAS 146 nullifies Emerging Issues Task Force Issue No. 94-3 (EITF 94-3), "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (Including Certain Costs Incurred in a Restructuring)". SFAS 146 requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred. Therefore, SFAS 146 eliminates the definition and requirements for recognition of exit costs in EITF 94-3. The provisions of SFAS 146 are effective for exit or disposal activities that are initiated after December 31, 2002. We will adopt the provisions of SFAS 146 for all exit activities, if any, initiated after December 31, 2002. We do not expect the adoption of this statement to have a material impact on our consolidated financial statements.

In November 2002, the FASB issued Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others" (the Interpretation) which expands on the accounting guidance of Statements No. 5, 57 and 107 and incorporates without change the provisions of FASB Interpretation No.34, which is being superseded. The Interpretation will significantly change current practice in the accounting for and disclosure of guarantees. Guarantees meeting the characteristics described in the Interpretation are to be recognized at fair value and significant disclosure rules have been implemented even if the likelihood of the guarantor making payments is remote. The disclosure requirements are effective for financial statements of interim or annual periods ending after December 15, 2002, while the initial measurement provisions are applicable on a prospective basis to guarantees issued or modified after December 31, 2002. Certain guarantees are excluded from the initial recognition provisions of the Interpretation, however specific disclosures are still required. We do not expect the adoption of this statement to have a material impact on our consolidated financial statements.

In December 2002, the FASB issued Statement of Financial Accounting Standard No. 148 (SFAS No. 148), "Accounting for Stock-Based Compensation-- Transition and Disclosure." SFAS No. 148 amends SFAS No. 123, "Accounting for Stock-Based Compensation," to provide alternative methods of transition to the fair value method of accounting for stock-based employee compensation. SFAS No. 148 also requires disclosure of the effects of an entity's accounting policy with respect to stock-based employee compensation on reported net income and earnings per share in annual and interim financial statements. SFAS No. 148 is effective for fiscal

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years ending after December 15, 2002. The disclosure requirements for interim financial statements containing condensed consolidated financial statements are effective for interim periods beginning after December 15, 2002. We adopted SFAS No. 148 in the fourth quarter of 2002

EITF Issue No. 00-21, Revenue Arrangements with Multiple Deliverables, addresses certain aspects of the accounting by a vendor for arrangements under which it will perform multiple revenue-generating activities and is effective for agreements entered into during fiscal periods beginning after June 15, 2003. In some arrangements, the different revenue-generating activities (deliverables) are sufficiently separable, and there exists sufficient evidence of their fair values to separately account for some or all of the deliverables (that is, there are separate units of accounting). In other arrangements, some or all of the deliverables are not independently functional, or there is not sufficient evidence of their fair values to account for them separately. The Company is currently evaluating the effect that the adoption of EITF Issue No. 00-21 will have on its financial position and results of operations.

### Critical Accounting Policies

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. Our preparation of this Annual Report on Form 10-K requires us to make estimates and assumptions that affect the reported amount of assets and liabilities, disclosure of contingent assets and liabilities at the date of our consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

#### Revenue Recognition

Biopharmaceutical revenues consist of license fees, contract research and milestone payments from alliances with pharmaceutical companies. GenomeVision(TM) Services revenues consist of government grants, fees received from custom gene sequencing and analysis services and subscription fees from the PathoGenome(TM) Database. Revenues from contract research, government grants, the PathoGenome(TM) Database subscription fees, and custom gene sequencing and analysis services are recognized over the respective contract periods as the services are performed, provided there is persuasive evidence of an arrangement, the fee is fixed or determinable and collection of the related receivable is probable. License fees are recognized ratably over the performance period in accordance with Staff Accounting Bulletin (SAB) No. 101, Revenue Recognition. Milestone payments will be recognized upon achievements of the milestone as long as the milestone is deemed to be substantive and we have no other performance obligations related to the milestone. Unbilled costs and fees represent revenue recognized prior to billing. Deferred revenue represents amounts received prior to revenue recognition.

#### Clinical Trial Accrual

Our clinical development trials related to Ramoplanin are primarily performed by outside parties. It is not unusual at the end of each accounting period for us to estimate both the total cost and time period of the trials and the percent completed as of that accounting date. We also adjust these estimates when final invoices are received. To date, these adjustments have not

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been material to our financial statements, and we believe that the estimates that we made as of December 31, 2002 are reflective of the actual expenses incurred as of that date. However, readers should be cautioned that the possibility exists that the timing or cost of the Ramoplanin clinical trials might be longer or shorter and cost more or less than we have estimated and that the associated financial adjustments would be reflected in future periods.

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### Results of Operations

Years Ended December 31, 2001 and 2002

#### Revenues

Total revenues decreased 36% from \$35,741,000 in 2001 to \$22,987,000 in 2002. Biopharmaceutical revenue decreased 58% from \$18,438,000 in 2001 to \$7,716,000 in 2002 primarily due to the absence in 2002 of milestone payments that were earned in 2001 under our product discovery alliances with Schering-Plough and Wyeth. The decrease in biopharmaceutical revenue also reflects lower sponsored research revenue as a result of the completion of our research obligations under our two anti-infective alliances with Schering-Plough in March 2002, as well as our strategic decision to seek to partner discovery programs at a later stage of development.

Revenue from GenomeVision(TM) Services decreased 12% from \$17,302,000 in 2001 to \$15,271,000 in 2002 primarily due to lower revenues recognized under our government grants with the National Human Genome Research Institute to participate in the Human Genome and Mouse (Rat) Genome sequencing projects, as well as lower subscription fees earned under our PathoGenome(TM) Database business as a result of third parties not renewing their database subscriptions.

#### Costs and Expenses

Total costs and expenses increased 16% from \$48,978,000 in 2001 to \$56,836,000 in 2002. Cost of services decreased 7% from \$16,153,000 in 2001 to \$15,019,000 in 2002 primarily due to decreased costs and expenses associated with the above mentioned decrease in GenomeVision(TM) Services revenue. The decrease consisted primarily of lower 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 35% from \$24,058,000 in 2001 to \$32,435,000 in 2002. This planned increase was primarily due to an increase in expenses incurred in the clinical development of Ramoplanin of approximately \$8,349,000, as well as increased investment in our internal drug discovery programs, specifically in the area of anti-infective and chronic human diseases, of \$2,105,000. These increases in research and development expenses were partially offset by a decline in research funded under our product discovery alliances of approximately \$2,077,000.

Selling, general and administrative expenses increased 7% from \$8,767,000 in 2001 to \$9,382,000 in 2002 reflecting an expansion in the areas of corporate development and sales and marketing, as well as severance related charges of approximately \$350,000 associated with our decision to reduce expenditures by eliminating 34 full-time staff positions in the areas of early stage research and administration.

#### Interest Income and Expense

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Interest income decreased 54% from \$3,839,000 in 2001 to \$1,769,000 in 2002 reflecting lower interest rate yields from investments, as well as a decrease in funds available for investment.

Interest expense increased 180% from \$692,000 in 2001 to \$1,936,000 in 2002. The increase in interest expense was due to an increase in our outstanding balances under long-term obligations from approximately \$5.6 million at December 31, 2001 to \$18.3 million at December 31, 2002. The increase in our long-term obligations resulted primarily from the March 2002 sale of convertible notes payable in a private placement transaction, which resulted in gross proceeds of \$15 million. Interest expense also includes approximately \$774,000 related to the amortization of deferred issuance costs and warrants issued in connection with the convertible notes payable.

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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 and Schering-Plough.

Revenue from GenomeVision(TM) 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 38% from \$11,715,000 in 2000 to \$16,153,000 in 2001 primarily due to increased costs and expenses associated with the above mentioned increase in GenomeVision(TM) Services revenue. 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 costs associated with the acquisition and clinical development of Ramoplanin of approximately \$5,549,000, as well as increased investment in our internal drug discovery programs of \$4,138,000, specifically in the area of anti-infectives and chronic human diseases.

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, 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)

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proceeds received from the sale of common stock through public offerings in 2000 and 2001, (ii) proceeds received from the exercise of stock options, and (iii) proceeds received from our employee stock purchase plan.

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.

### Liquidity and Capital Resources

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

As of December 31, 2002, we had cash, cash equivalents and short-term and long-term marketable securities of approximately \$50,866,000. On March 5, 2002, we sold convertible notes payable to two institutional investors in a private placement transaction, raising \$15 million in gross proceeds. The convertible notes payable may be converted into shares of our common stock at the option of the holder, at a price of \$8.00 per share,

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subject to certain adjustments. The maturity date of the convertible notes payable is December 31, 2004, provided, that if any time on or after December 31, 2003 we maintain a net cash balance (i.e., cash and cash equivalents less obligations for borrowed money bearing interest) of less than \$35 million, then the holders of the convertible notes payable can require that all or any part of the outstanding principal balance of the notes payable plus all accrued but unpaid interest be repaid. Interest on the notes payable accrues at 6% annually and the interest is payable, in cash or in stock, semi-annually on June 30 and December 31 of each year. As of December 31, 2002, two interest payments on the convertible notes payable had become due and were paid by issuing 494,083 shares of our common stock to the holders of the notes payable, of which 120,986 and 373,107 shares were issued in July 2002 and January 2003, respectively. The investors also received a warrant to purchase up to an aggregate of 487,500 shares of common stock at an exercise price of \$8.00 per share, subject to certain adjustments. The warrant is exercisable at the time the convertible notes payable are converted or if certain other redemptions or repayments of the convertible notes payable occur and will terminate upon the earlier of four years from date of such conversion or December 31, 2008. The warrant was valued, using the Black-Scholes option pricing model, at \$1,736,000. The amount was recorded as a discount to long-term debt and will be amortized to interest expense over the term of the convertible notes payable. Additionally, we are obligated to issue a warrant to purchase up to 100,000 shares of common stock at an exercise price of \$15.00 per share to our placement agent in this transaction. The warrant is exercisable over a three-year term which commenced upon the closing of the notes payable transaction. This warrant was valued, using the Black-Scholes option pricing model, at \$244,000. This amount is included in deferred issuance costs and will be amortized to interest expense over the term of the convertible notes payable. In 2002, we also issued 154,076 shares of common stock related to the exercise of stock options and our employee stock purchase plan, resulting in proceeds received of approximately \$466,000.

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

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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.

We received payments of approximately \$17,406,000, \$19,500,000 and \$6,454,000 in 2000, 2001 and 2002, respectively, from our product discovery partners consisting of up-front license fees, contract research funding, subscription fee, milestone payments and expense reimbursement.

We have various arrangements under which we have financed certain office and laboratory equipment and leasehold improvements. We had an aggregate of approximately \$4,504,000 outstanding under our borrowing arrangements at December 31, 2002. This amount is repayable over the next 26 months, with \$2,624,000 repayable over the next 12 months. Under these arrangements, we are required to maintain certain financial ratios, including minimum levels of unrestricted cash. We had no additional borrowing capacity under these capital lease agreements at December 31, 2002.

Our operating activities used cash of approximately \$26,428,000 in 2002 primarily due to an increase in our net loss, accounts receivables, unbilled costs and fees and deferred revenue. These uses of cash were partially offset by a decrease in interest receivable, prepaid expenses and other current assets, as well as an increase in accounts payables and accrued liabilities. Our operating activities used cash of approximately \$3,101,000 in 2001 and provided cash of approximately \$2,506,000 in 2000.

Our investing activities provided cash of approximately \$1,226,000 and \$17,266,000 in 2002 and 2001, respectively, through the conversion of marketable securities to cash and cash equivalents, partially offset by purchases of marketable securities, equipment and additions to leasehold improvements, as well as an increase in other assets in 2002. The increase in other assets in 2002 reflects the inclusion of deferred issuance costs

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associated with the convertible notes payable, which will be amortized to interest expense over the term of the convertible notes payable. Our investing activities used cash of approximately \$48,755,000 in 2000 to purchase marketable securities, equipment and additions to leasehold improvements, partially offset by the conversion of marketable securities to cash and cash equivalents and the sale of certain laboratory equipment.

Capital expenditures totaled \$3,818,000 during 2002 primarily consisting of purchases of laboratory, computer, and office equipment. We amended an existing capital lease financing arrangement to finance the majority of these capital expenditures. We currently estimate that we will acquire approximately \$1,000,000 in capital equipment in 2003 consisting primarily of computers, laboratory equipment, and additions to leasehold improvements.

Our financing activities provided cash of approximately \$14,626,000 in 2002 primarily from proceeds received from the sale of convertible notes payable totaling \$15 million in gross proceeds, proceeds received from entering into an additional credit line for \$3,500,000, of which \$500,000 was used to refinance a portion of an existing line of credit, as well as proceeds received from issuances of stock under the employee stock purchase plan. These proceeds from

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financing activities were partially offset by payments of long-term obligations of \$4,629,000. Our financing activities provided cash of approximately \$545,000 and \$47,328,000 in 2001 and 2000, respectively, 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, 2002, we had net operating loss and tax credits (investment and research) carryforwards of approximately \$120,307,000 and \$9,084,000, respectively, available to reduce federal taxable income and federal income taxes, respectively, if any. Net operating loss carryforwards are subject to review and possible adjustment by the Internal Revenue Service and may be limited, in the event of certain cumulative changes in ownership interests of significant shareholders over a three-year period in excess of 50%. Additionally, certain of our losses have begun to expire due to the limitations of the carryforward period.

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

We plan to continue to invest in our internal research and development programs, primarily in our lead candidate, Ramoplanin, currently in a Phase III clinical trial for the prevention of bloodstream infections caused by vancomycin-resistant enterococci (VRE), and a Phase II clinical trial to assess the safety and efficacy of Ramoplanin to treat *Clostridium difficile*-associated diarrhea (CDAD). We expect to incur approximately \$10-15 million in clinical development expenditures during 2003.

We plan to seek additional funding in the next 12 months through public or private financing in order to fund our clinical development and research projects. Additional financing may not be available when needed or if available, it may not be on terms acceptable to us. Any additional capital that we raise by issuing equity or convertible debt securities will dilute the ownership of existing stockholders.

### Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

As specified in our investment policy guidelines, investments are made primarily in high-grade corporate bonds with effective maturities of two years or less, and U.S. government agency securities. These investments are subject to risk of default, changes in credit rating and changes in market value. These investments are also subject to interest rate risk and will decrease in value if market interest rates increase. A hypothetical 100 basis point increase in interest rates would result in an approximate \$366,000 decrease in the fair value of our investments as of December 31, 2002. However, the conservative nature of our investments mitigates our interest rate exposure, and our investment policy limits the amount of our 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.

We are also subject to interest rate risk through our borrowing activities. We use United States dollar denominated borrowings to fund certain investment needs. As of December 31, 2002, we had \$2.6 million outstanding under our \$3,500,000 line of credit that bears interest at the prevailing LIBOR rate (2.06% at December 31, 2002) plus 1.50%. A 10% increase in market rates would



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have increased our interest expense by approximately \$9,000 in fiscal 2002.

As of December 31, 2002, we did not have any financing arrangements that were not reflected in our balance sheet.

In 2000, we entered into two separate interest-rate swap agreements with a bank for an aggregate amount of approximately \$1,900,000. Under these agreements, we paid a fixed rate of 8.78% and received a variable rate tied to the one month LIBOR rate. As of December 31, 2001, the variable rate was 3.83%. These swap agreements met the required criteria set forth in SFAS No. 133 to use special hedge accounting, and we 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 do not currently own any derivative financial instruments.

The interest rates on our convertible notes payable and capital lease obligations are fixed and therefore not subject to interest rate risk.

### 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 15(a) below.

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## PART III

Pursuant to General Instruction G(3) to Form 10-K, 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 May 9, 2003.

### Item 14. Controls and Procedures.

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

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## PART IV

### Item 15. Exhibits, Financial Statement Schedules and Reports on Form 8-K

(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.

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### (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(14)
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 Wind Fund Ltd.(35)
4.3	Form of Warrant received by Smithfield Fiduciary LLC and The Tail Wind Fund, Ltd.(35)
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(6)
10.7	Amendment dated November 4, 1986 to the Genome Therapeutics Corp. (f/k/a Collaborative Research) Incentive Savings 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(13)
10.16	Lease dated June 3, 1993 relating to certain property in Waltham, Massachusetts(13)
10.19	Employment Agreement with Robert J. Hennessey(13)
10.22	Lease Amendment dated August 1, 1994 relating to certain property in Waltham, MA(14)
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 August 31, 1995(16) *
10.29	Collaboration and License Agreement between the Company, Schering Corporation and Schering Plough Ltd., dated as of December 6, 1995(18) *

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- 10.30 Form of director Stock Option Agreement and schedule of director options granted(17)
- 10.37 Lease amendment dated November 15, 1996 to certain property in Waltham, MA(19)

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Exhibit No. -----	Description -----
10.38	Collaboration and License Agreement between the Company, Schering Corporation and Schering Plough Ltd., dated as of December 20, 1996(20)*
10.39	Credit agreement between the Company and Fleet National Bank dated February 28, 1997(21)
10.40	Credit agreement between the Company and U S Trust (f/k/a Sumitomo Bank, Limited) dated J 1997(22)
10.41	Collaboration and License Agreement between the Company and Schering Corporation, dated September 22, 1997(23)*
10.42	Collaboration and License Agreement between the Company and Schering-Plough Ltd. dated September 22, 1997(23)*
10.43	Credit modification agreement between the Company and Fleet National Bank, dated March 9, 1998(24)
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, Inc., acting through its Wyeth-Ayerst Division, dated December 20, 1999(27)
10.49	Collaboration and License Agreement between Genome Therapeutics Corporation and bioMerieux Incorporated dated as of September 30, 1999(29)
10.50	Registration Rights Agreement between the Company and bioMerieux Alliance sa dated September 30, 1999(30)
10.51	Compound Discovery Collaboration Agreement, dated October 17, 2000 between the Company and ArQule, Inc.(31)*
10.52	2001 Incentive Plan(32)
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 Wind Fund

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Ltd. and the Company(35)

- 10.59 Registration Rights Agreement dated March 5, 2002 among Smithfield Fiduciary LLC, The Tai Wind Fund, Ltd. and the 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., dated October 2001(37)\*
- 10.62 Research Collaboration and License Agreement between the Company and Amgen Inc., dated December 20, 2002(38)\*
- 10.63 Stock Purchase Agreement between the Company and Amgen Inc., dated December 20, 2002(38)\*
- 10.64 Letter Agreement between the Company and Biosearch Italia, S.P.A., dated October 22, 2002
- 23.1 Consent of Ernst & Young LLP Independent Public Accounts(38)
- 99.1 Risk Factors(38)
- 99.2 Certification of the Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxle
- 99.3 Certification of the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxle

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

- (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.
- (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 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

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- 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 the 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.

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- (30) Filed as an exhibit to the Company's Registration Statement on Forms S-3 (333-32614) and incorporated herein by reference.
- (31) Filed as an exhibit to the Company's 10-K for the quarter ended November 25, 2000 and incorporated herein by reference.
- (32) Filed as an 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 as an exhibit to the Company's 10-K for the fiscal year ended December 31, 2001 and incorporated herein by reference.
- (37) Filed as an exhibit to the Company's 10-K/A2 for the fiscal year ended December 31, 2001 and incorporated herein by reference.
- (38) Filed herewith.

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### SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, Genome Therapeutics Corp. has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 31, 2003.

GENOME THERAPEUTICS CORP.

/s/ STEPHEN COHEN

-----  
Stephen Cohen  
Senior Vice President and Chief  
Financial Officer

GENOME THERAPEUTICS CORP. AND SUBSIDIARY

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

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

1. I have reviewed this annual report on Form 10-K of Genome Therapeutics Corp.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

c) Presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal

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controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

/s/ STEVEN M. RAUSCHER  
Steven M. Rauscher  
President & Chief Executive  
Officer

Date: March 31, 2003

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GENOME THERAPEUTICS CORP. AND SUBSIDIARY

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

I, Stephen Cohen, Senior Vice President & Chief Financial Officer, certify that:

1. I have reviewed this annual report on Form 10-K of Genome Therapeutics Corp.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

c) Presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability

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to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

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

/s/ Stephen Cohen  
Stephen Cohen  
Senior Vice President & Chief  
Financial Officer

Date: March 31, 2003

GENOME THERAPEUTICS CORP. AND SUBSIDIARY  
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REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

The Board of Directors and Stockholders of  
Genome Therapeutics Corp.

We have audited the accompanying consolidated balance sheet of Genome Therapeutics Corp. as of December 31, 2002, and the related statements of operations, shareholders' equity and comprehensive income, and cash flows for



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the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit. The consolidated financial statements of Genome Therapeutics Corp. as of December 31, 2001 were audited by other auditors who have ceased operations and whose report dated June 18, 2002, except with respect to the matter discussed in note 1(m) as to which the date is June 18, 2002, expressed an unqualified opinion on those statements.

We conducted our audit 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 financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides 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. as of December 31, 2002, and the results of its operations, stockholders' equity, and cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States.

/s/ ERNST & YOUNG LLP

Boston, Massachusetts  
February 18, 2003, except with respect to Note 13, as to which  
the date is March 14, 2003

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This is a copy of a report previously issued by Andersen and Andersen has not reissued the report.

### 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 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

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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 (except with respect to the matter discussed in Note 1(m) as to which the date is June 18, 2002)

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### GENOME THERAPEUTICS CORP. AND SUBSIDIARY CONSOLIDATED BALANCE SHEETS

	December 31,	
	2001	2002
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents.....	\$ 24,805,385	\$ 14,228
Marketable securities (held-to-maturity).....	29,961,540	32,584
Marketable securities (available-for-sale).....	--	485
Interest receivable.....	1,074,726	784
Accounts receivable.....	513,885	2,043
Unbilled costs and fees.....	164,465	714
Prepaid expenses and other current assets.....	1,583,320	444
Total current assets.....	58,103,321	51,285
Property and Equipment, at cost:		
Laboratory and scientific equipment.....	20,918,535	21,906
Leasehold improvements.....	8,798,842	8,923
Equipment and furniture.....	1,267,854	1,281
Total property and equipment.....	30,985,231	32,112
Less--Accumulated depreciation.....	19,091,703	21,973
Total property and equipment, net.....	11,893,528	10,138
Restricted Cash (Note 2).....	200,000	
Long-term Marketable Securities (held-to-maturity).....	11,839,045	3,567
Warrant (available-for-sale).....	535,279	
Other Assets.....	168,425	853
	\$ 82,739,598	\$ 65,845
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current Liabilities:		
Current maturities of long-term obligations.....	\$ 3,571,578	\$ 2,623
Accounts payable.....	2,092,593	2,175
Accrued expenses (Note 12).....	4,832,713	8,408
Deferred revenue.....	3,449,959	1,566

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Total current liabilities.....	13,946,843	14,774
Long-term Obligations, net of current maturities.....	2,060,817	15,654
Commitments (Note 4 and 10)		
Shareholders' Equity:		
Common stock, \$0.10 par value--Authorized--50,000,000 shares Issued and outstanding--22,772,170 and 23,066,072 shares in 2001 and 2002, respectively.....	2,277,217	2,306
Additional paid-in capital.....	156,214,735	158,976
Accumulated deficit.....	(91,758,375)	(125,775)
Deferred compensation and note receivable from officer (Note 6(e))....	(506,088)	(376)
Accumulated other comprehensive income.....	504,449	285
Total shareholders' equity.....	66,731,938	35,416
	\$ 82,739,598	\$ 65,845
	=====	=====

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 Ended December 31,		
	2000	2001	2002
	-----	-----	-----
Revenues:			
Biopharmaceutical.....	\$11,851,091	\$ 18,438,286	\$ 7,715,992
GenomeVision(TM) Services.....	13,594,143	17,302,239	15,270,863
Total revenues.....	25,445,234	35,740,525	22,986,855
Costs and Expenses:			
Cost of services.....	11,714,955	16,152,707	15,019,436
Research and development.....	15,190,531	24,057,760	32,435,086
Selling, general and administrative.....	6,874,579	8,767,229	9,381,931
Total costs and expenses.....	33,780,065	48,977,696	56,836,453
Loss from operations.....	(8,334,831)	(13,237,171)	(33,849,598)
Interest Income (Expense):			
Interest income.....	3,330,625	3,839,260	1,768,690
Interest expense.....	(842,633)	(692,391)	(1,936,117)
Net interest income (expense).....	2,487,992	3,146,869	(167,427)
Net loss.....	\$ (5,846,839)	\$ (10,090,302)	\$ (34,017,025)
	=====	=====	=====
Net Loss per Common Share:			
Basic and diluted.....	\$ (0.27)	\$ (0.45)	\$ (1.48)
	=====	=====	=====
Weighted Average Common Shares Outstanding:			

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Basic and diluted..... 21,376,685      22,572,427      22,920,875  
 =====

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

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GENOME THERAPEUTICS CORP. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY AND COMPREHENSIVE INCOME

	Common Stock		
	Shares	\$0.10 Par Value	Additional Paid-In Capital
	-----	-----	-----
Balance, December 31, 1999.....	19,499,715	\$1,949,971	\$103,836,131
	=====	=====	=====
Sale of common stock, net of issuance costs of \$718,066.....	1,500,000	150,000	44,572,729
Exercise of stock options.....	1,280,612	128,062	3,184,327
Issuance of stock under employee stock purchase plan.....	8,331	833	214,723
Deferred compensation from grant of stock options.....	--	--	1,377,161
Amortization of deferred compensation and other stock-based compensation expense.....	--	--	--
Reversal of deferred compensation related to cancellation of stock options.....	--	--	(461,783)
Net loss.....	--	--	--
	-----	-----	-----
Balance, December 31, 2000.....	22,288,658	2,228,866	152,723,288
	=====	=====	=====
Sale of common stock, net of issuance costs of \$44,622.....	127,500	12,750	1,693,017
Exercise of stock options.....	251,354	25,135	736,584
Issuance of stock under employee stock purchase plan.....	74,596	7,460	434,410
Issuance of restricted common stock and loan to officer (Note 6e).....	24,000	2,400	(2,400)
Deferred compensation from grant of stock options.....	--	--	647,942
Issuance of stock under directors deferred stock plan..	6,062	606	(606)
Amortization of deferred compensation and other stock-based compensation expense.....	--	--	--
Reversal of deferred compensation related to cancellation of stock options.....	--	--	(17,500)
Unrealized gain on long-term investment (available for sale).....	--	--	--
Unrealized loss on derivative instruments.....	--	--	--
Net loss.....	--	--	--
	-----	-----	-----
Balance, December 31, 2001.....	22,772,170	2,277,217	156,214,735

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	=====	=====	=====
Exercise of stock options.....	10,614	1,061	11,987
Issuance of stock under employee stock purchase plan.....	143,462	14,346	438,587
Issuance of stock related to interest payable under convertible notes.....	120,986	12,099	276,394
Deferred compensation from grant of stock options.....	--	--	300,740
Issuance of stock under directors deferred stock plan..	18,840	1,884	(1,884)
Amortization of deferred compensation and other stock-based compensation expense.....	--	--	--
Value of warrants issued in connection with convertible notes.....	--	--	1,736,059
Unrealized loss on short-term investment (available for sale).....	--	--	--
Reversal of unrealized loss on derivative instruments..	--	--	--
Net loss.....	--	--	--
Balance, December 31, 2002.....	23,066,072	\$2,306,607	\$158,976,618

	Accumulated Other Comprehensive Income	Total Share- holders' Equity	Compre- hensive Income
	-----	-----	-----
Balance, December 31, 1999.....	--	\$ 28,846,957	\$ (3,940,000)
Sale of common stock, net of issuance costs of \$718,066.....	--	44,722,729	
Exercise of stock options.....	--	3,312,389	
Issuance of stock under employee stock purchase plan.....	--	215,556	
Deferred compensation from grant of stock options.....	--	--	
Amortization of deferred compensation and other stock-based compensation expense.....	--	1,436,660	
Reversal of deferred compensation related to cancellation of stock options.....	--	--	
Net loss.....	--	(5,846,839)	(5,846,839)
Balance, December 31, 2000.....	--	72,687,452	(5,846,839)
Sale of common stock, net of issuance costs of \$44,622.....	--	1,705,767	
Exercise of stock options.....	--	761,719	
Issuance of stock under employee stock purchase plan.....	--	441,870	
Issuance of restricted common stock and loan to officer (Note 6e).....	--	(163,000)	
Deferred compensation from grant of stock options.....	--	--	
Issuance of stock under directors deferred stock plan..	--	--	
Amortization of deferred compensation and other stock-based compensation expense.....	--	883,983	
Reversal of deferred compensation related to cancellation of stock options.....	--	--	
Unrealized gain on long-term investment (available for sale).....	535,279	535,279	535,279
Unrealized loss on derivative instruments.....	(30,830)	(30,830)	(30,830)

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Net loss.....	--	(10,090,302)	(10,090,302)
	-----	-----	-----
Balance, December 31, 2001.....	504,449	66,731,938	(9,585,800)
	=====	=====	=====
Exercise of stock options.....	--	13,048	
Issuance of stock under employee stock purchase plan.....	--	452,933	
Issuance of stock related to interest payable under convertible notes.....	--	288,493	
Deferred compensation from grant of stock options.....	--	--	
Issuance of stock under directors deferred stock plan..	--	--	
Amortization of deferred compensation and other stock-based compensation expense.....	--	430,338	
Value of warrants issued in connection with convertible notes.....	--	1,736,059	
Unrealized loss on short-term investment (available for sale).....	(249,890)	(249,890)	(249,890)
Reversal of unrealized loss on derivative instruments..	30,830	30,830	30,830
Net loss.....	--	(34,017,025)	(34,017,025)
	-----	-----	-----
Balance, December 31, 2002.....	\$ 285,389	\$ 35,416,724	\$ (34,236,000)
	=====	=====	=====

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

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GENOME THERAPEUTICS CORP. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year
	-----
	2000
	-----
Cash Flows from Operating Activities:	
Net loss.....	\$ (5,846,839)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities--	
Depreciation and amortization.....	4,471,722
Non-cash interest expense.....	--
Loss (Gain) on disposal of equipment and leasehold improvements.....	160,624
Amortization of deferred compensation.....	1,436,660
Changes in assets and liabilities--	
Interest receivable.....	(612,005)
Accounts receivable.....	(10,787)
Unbilled costs and fees.....	1,220,195
Prepaid expenses and other current assets.....	(323,730)
Accounts payable.....	305,954
Accrued expenses.....	1,049,809
Deferred revenue.....	654,545
	-----
Net cash provided by (used in) operating activities.....	2,506,148
	-----

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Cash Flows from Investing Activities:	
Purchases of marketable securities.....	(69,013,466)
Proceeds from sale of marketable securities.....	23,860,411
Purchases of property and equipment.....	(4,152,675)
Proceeds from sale of property and equipment.....	504,583
Decrease in restricted cash.....	--
Decrease (increase) in other assets.....	46,167
	-----
Net cash (used in) provided by investing activities.....	(48,754,980)
	-----
Cash Flows from Financing Activities:	
Proceeds from sale of common stock.....	44,722,729
Proceeds from exercise of stock options.....	3,312,389
Proceeds from issuance of stock under the employee stock purchase plan.....	215,556
Note receivable from officer.....	120,000
Gross proceeds from convertible notes payable.....	--
Proceeds from borrowings on equipment financing arrangements.....	3,691,840
Payments on long-term obligations.....	(4,734,876)
	-----
Net cash provided by financing activities.....	47,327,638
	-----
Net Increase (Decrease) in Cash and Cash Equivalents.....	1,078,806
Cash and Cash Equivalents, beginning of year.....	9,017,011
	-----
Cash and Cash Equivalents, end of year.....	\$ 10,095,817
	=====
Supplemental Disclosure of Cash Flow Information:	
Interest paid during the year.....	\$ 842,633
	=====
Income taxes paid during the year.....	\$ 8,231
	=====
Supplemental Disclosure of Noncash Investing and Financing Activities:	
Equipment acquired under capital leases.....	\$ 3,691,840
	=====
Unrealized gain (loss) on marketable securities.....	\$ --
	=====
Issuance of warrant in connection with convertible notes payable.....	\$ --
	=====
Unrealized (loss) gain on derivative instruments.....	\$ --
	=====
Issuance of common stock related to interest payable under convertible notes...	\$ --
	=====

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

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GENOME THERAPEUTICS CORP. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(1) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Genome Therapeutics Corp. and subsidiary (the Company) is a biopharmaceutical company focused on the discovery, development and commercialization of pharmaceutical and diagnostic products. Its strategic goal is to directly participate in the commercialization of products that are used primarily in hospitals. For diseases treated by larger physician audiences, the

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Company seeks to discover, develop and commercialize products through alliances with major pharmaceutical companies.

The Company has nine established product development programs. The Company is managing the development and commercialization of its lead product candidate, Ramoplanin, in the United States and Canada. This product is in a Phase III clinical trial for the prevention of bloodstream infections caused by vancomycin-resistant enterococci (VRE) and a Phase II trial for the treatment of patients with Clostridium difficile-associated diarrhea (CDAD). The Company has seven product discovery and development alliances with pharmaceutical companies including Amgen, AstraZeneca, bioMerieux, Schering-Plough and Wyeth. In addition, the Company has a portfolio of internal drug discovery programs. During 2002, the Company also maintained an active service business, GenomeVision/TM/ Services, providing drug discovery services to pharmaceutical and biotechnology companies and to the National Human Genome Research Institute. (See Note 13)

The Company concentrates its product discovery, development and commercialization efforts in two principal areas:

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

The accompanying consolidated financial statements reflect the application of certain accounting policies, as described in this note and elsewhere in the accompanying notes to the consolidated financial statements.

### (a) Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, Collaborative Securities Corp. (a Massachusetts Securities Corporation). All intercompany accounts and transactions have been eliminated in consolidation.

### (b) Revenue Recognition

Biopharmaceutical revenues consist of license fees, contract research and milestone payments from alliances with pharmaceutical companies. GenomeVision/TM/ Services revenues consist of government grants, fees received from custom gene sequencing and analysis services and subscription fees from the PathoGenome/TM/ Database. Revenues from contract research, government grants, the PathoGenome/TM/ Database subscription fees, and custom gene sequencing and analysis services are recognized over the respective contract periods as the services are performed, provided there is persuasive evidence of an arrangement, the fee is fixed or determinable and collection of the related receivable is probable. License fees are recognized ratably over the performance period in accordance with Staff Accounting Bulletin (SAB) No. 101, Revenue Recognition. Milestone payments will be recognized upon achievement of the milestone as long as the milestone is deemed to be substantive and the Company has no other performance obligations related to the milestone. Unbilled costs and fees represent revenue recognized prior to billing. Deferred revenue represents amounts received prior to revenue recognition.

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GENOME THERAPEUTICS CORP. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)



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### (c) Property and Equipment

Property and equipment, including leasehold improvements, are depreciated over their estimated useful lives using the straight-line method. The estimated useful life for leasehold improvements is the lesser of the term of the lease or the estimated useful life of the assets. The majority of the Company's equipment and leasehold improvements are financed through bank lines of credit.

	Estimated Useful Life
Laboratory Equipment.....	5 Years
Computer Equipment & Licenses	3 Years
Office Equipment.....	5 Years
Furniture & Fixtures.....	5 Years

Depreciation expense was approximately \$4,472,000, \$4,807,000 and \$5,545,000 for the years ended December 31, 2000, 2001, and 2002, respectively.

### (d) Net Loss Per Share

Basic and diluted earnings per share were determined by dividing net loss by the weighted average shares outstanding during the period. Diluted loss per share is the same as basic loss per share for all periods presented, as the effect of the potential common stock is antidilutive. Antidilutive securities which consist of stock options, securities sold under the Company's employee stock purchase plan, directors' deferred stock, warrants and unvested restricted stock that are not included in diluted net loss per share were 3,247,316, 3,746,794 and 5,322,897 shares during the years ended December 31, 2000, 2001 and 2002, respectively.

### (e) Concentration of Credit Risk

SFAS No. 105, Disclosure of Information about Financial Instruments with Off-Balance-Sheet Risk and Financial Instruments with Concentrations of Credit Risk, requires disclosure of any significant off-balance-sheet and credit risk concentrations. The Company has no off-balance-sheet or concentrations of credit risk such as foreign exchange contracts, options contracts or other foreign hedging arrangements. The Company maintains its cash and cash equivalents and investment balances with several nonaffiliated institutions.

The Company maintains reserves for the potential write-off of accounts receivable. To date, the Company has not written off any significant accounts.

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

Year ended December 31,	Number of Significant Customers	Percentage of Total Revenues		
		A	B	C
2000.....	2	35%	36%	--
2001.....	3	31%	36%	18%

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2002..... 2 23% 46% --

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GENOME THERAPEUTICS CORP. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

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

At December 31,	Percentage of Total Accounts Receivable				
	B	D	E	F	G
2000.....	87%	--	--	--	--
2001.....	--	37%	29%	--	--
2002.....	23%	--	--	27%	37%

(f) Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

(g) Financial Instruments

The estimated fair value of the Company's financial instruments, which includes cash and cash equivalents, short-term and long-term marketable securities, accounts receivable, accounts payable and long-term debt, approximates the carrying values of these instruments.

(h) Reclassifications

The Company has reclassified certain prior-year information to conform with the current year's presentation.

(i) Comprehensive Income (Loss)

The Company follows the provisions of SFAS No. 130, Reporting Comprehensive Income. SFAS No. 130 requires disclosure of all components of comprehensive income (loss) on an annual and interim basis. Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from nonowner sources. In 2001, the Company recorded approximately \$535,000 to comprehensive income related to the value of a warrant received in connection with its collaboration agreement with Versicor Inc., which subsequently merged with Biosearch Italia S.p.A and changed its name to Vicuron Pharmaceuticals Inc. (Vicuron). In 2002, the

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Company recorded approximately \$250,000 to comprehensive loss related to the decrease in the fair market value of common shares of Vicuron received in connection with the exercise of this warrant. These common shares are classified as available for sale short-term marketable securities in the accompanying balance sheet. See Note 2 for further discussion.

### (j) Segment Reporting

The Company follows the provisions of SFAS No. 131, Disclosures about Segments of an Enterprise and Related Information. SFAS No. 131 establishes standards for reporting information regarding operating segments in annual financial statements and requires selected information for those segments to be presented in interim financial reports issued to stockholders. SFAS No. 131 also establishes standards for related disclosures about products and services and geographic areas. Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision

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### GENOME THERAPEUTICS CORP. AND SUBSIDIARY

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

maker, or decision-making group, in making decisions as to how to allocate resources and assess performance. The Company's chief decision makers, as defined under SFAS No. 131, are the chief executive officer and chief financial officer. To date, the Company has viewed its operations and manages its business as principally two operating segments: GenomeVision/TM/ Services and Biopharmaceutical. As a result, the financial information disclosed herein represents all of the material financial information related to the Company's two operating segments. All of the Company's revenues are generated in the United States and all assets are located in the United States.

	GenomeVision (TM) Services	Biopharmaceutical	Total
	-----	-----	-----
2000			
Revenues.....	\$13,594,143	\$11,851,091	\$25,445,234
Gross profit.....	1,879,188	3,715,045	5,594,233
Company-funded research & development	--	7,054,485	7,054,485
2001			
Revenues.....	\$17,302,239	\$18,438,286	\$35,740,525
Gross profit.....	1,149,532	11,122,807	12,272,339
Company-funded research & development	--	16,742,281	16,742,281
2002			
Revenues.....	\$15,270,863	\$ 7,715,992	\$22,986,855
Gross profit.....	251,427	2,477,466	2,728,893
Company-funded research & development	--	27,196,560	27,196,560

The Company does not allocate assets by its operating segments.

### (k) Recent Accounting Pronouncements

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In August 2001, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standard No. 144 (SFAS No. 144), "Accounting for the Impairment or Disposal of Long-Lived Assets," which addresses financial accounting and reporting for the impairment or disposal of long-lived assets and supercedes SFAS No. 121, "Accounting for Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of" and the accounting and reporting provisions of APB Opinion No. 30, "Reporting the Results of Operations," for a disposal of a segment of a business. SFAS No. 144 is effective for fiscal years beginning after December 15, 2001, with transition provisions for assets "held for sale" that were initially recorded under previous models (APB No. 30 or SFAS No. 121) and do not meet the new "held for sale" criteria. The Company adopted SFAS No. 144 in the first quarter of 2002.

In May 2002, the FASB issued Statement of Financial Accounting Standard No. 145 ("SFAS 145"), "Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections". Among other things, SFAS 145 rescinds Statement of Financial Accounting Standards No. 4 (SFAS 4), "Reporting Gains and Losses from Extinguishment of Debt" and eliminates the requirement that gains and losses from the extinguishment of debt be classified as an extraordinary item, net of related income tax effects, unless the criteria in Accounting Principles Board 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" are met. Adoption of this statement is generally required in fiscal years beginning after May 15, 2002. The Company does not expect the adoption of this statement to have a material impact on its consolidated financial statements.

In June 2002, the FASB issued Statement of Financial Accounting Standard No. 146 (SFAS 146), "Accounting for Costs Associated With Exit or Disposal Activities". SFAS 146 nullifies Emerging Issues Task

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### GENOME THERAPEUTICS CORP. AND SUBSIDIARY

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

Force Issue No. 94-3 (EITF 94-3), "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (Including Certain Costs Incurred in a Restructuring)". SFAS 146 requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred. Therefore, SFAS 146 eliminates the definition and requirements for recognition of exit costs in EITF 94-3. The provisions of SFAS 146 are effective for exit or disposal activities that are initiated after December 31, 2002. We will adopt the provisions of SFAS 146 for all exit activities, if any, initiated after December 31, 2002. The Company does not expect the adoption of this statement to have a material impact on its consolidated financial statements.

In November 2002, the FASB issued Interpretation No. 45, Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others (the Interpretation) which expands on the accounting guidance of Statements No. 5, 57 and 107 and incorporates without change the provisions of FASB Interpretation No. 34, which is being superseded. The Interpretation will significantly change current practice in the accounting for and disclosure of guarantees. Guarantees meeting the characteristics described in the Interpretation are to be recognized at fair value and significant disclosure rules have been implemented even if the likelihood of the guarantor making payments is remote. The disclosure requirements are effective for financial statements of interim or annual periods ending after

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December 15, 2002, while the initial measurement provisions are applicable on a prospective basis to guarantees issued or modified after December 31, 2002. Certain guarantees are excluded from the initial recognition provisions of the Interpretation, however specific disclosures are still required. The Company does not expect the adoption of this statement to have a material impact on its consolidated financial statements.

In December 2002, the FASB issued Statement of Financial Accounting Standard No. 148 (SFAS No. 148), "Accounting for Stock-Based Compensation--Transition and Disclosure." SFAS No. 148 amends SFAS No. 123, "Accounting for Stock-Based Compensation," to provide alternative methods of transition to the fair value method of accounting for stock-based employee compensation. SFAS No. 148 also requires disclosure of the effects of an entity's accounting policy with respect to stock-based employee compensation on reported net income and earnings per share in annual and interim financial statements. SFAS No. 148 is effective for fiscal years ending after December 15, 2002. The disclosure requirements for interim financial statements containing condensed consolidated financial statements are effective for interim periods beginning after December 15, 2002. The Company adopted SFAS No. 148 in the fourth quarter of 2002.

EITF Issue No. 00-21, Revenue Arrangements with Multiple Deliverables, addresses certain aspects of the accounting by a vendor for arrangements under which it will perform multiple revenue-generating activities and is effective for agreements entered into during fiscal periods beginning after June 15, 2003. In some arrangements, the different revenue-generating activities (deliverables) are sufficiently separable, and there exists sufficient evidence of their fair values to separately account for some or all of the deliverables (that is, there are separate units of accounting). In other arrangements, some or all of the deliverables are not independently functional, or there is not sufficient evidence of their fair values to account for them separately. The Company is currently evaluating the effect that the adoption of EITF Issue No. 00-21 will have on its financial position and results of operations.

### (1) Pro Forma Disclosure of Stock-based Compensation

The Company follows Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" (APB 25) and related interpretations, in accounting for stock-based compensation issued to employees, rather than the alternative fair value accounting method provided for under SFAS No. 123, "Accounting for Stock-Based Compensation". Under APB 25, when the exercise price of options granted under

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## GENOME THERAPEUTICS CORP. AND SUBSIDIARY

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

these plans equals the market price of the underlying stock on the date of grant, no compensation expense is required. In accordance with Emerging Issues Task Force ("EITF") 96-18, the Company records compensation expense equal to the fair value of options granted to non-employees over the vesting period, which is generally the period of service.

The following tables illustrate the assumptions used and the effect on net loss and net loss per share if the Company had applied the fair value recognition provisions of SFAS No. 123 to employee stock-based compensation. The Company has computed the pro forma disclosures required under SFAS No. 123 and SFAS No, 148 for all employee stock options granted using the Black-Scholes option pricing model prescribed by SFAS No. 123.

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	2000	2001	2002
	-----	-----	-----
Risk-free interest rate.....	5.36%-6.71%	4.31%-5.24%	3.50%-5.14%
Expected dividend yield.....	--	--	--
Expected life.....	5 years	5 years	5 years
Expected volatility.....	87%	87%	84%
Weighted average grant date fair market value	\$11.45	\$6.25	\$1.83

	2000	2001	2002
	-----	-----	-----
Net loss as reported.....	\$ (5,846,839)	\$ (10,090,302)	\$ (34,000,000)
Add: Stock-based employee compensation cost, included in the determination of net loss as reported.....	1,436,660	883,983	4,000,000
Less: Total stock-based compensation cost determined under fair value based method for all employee awards.....	(2,765,385)	(7,494,633)	(4,900,000)
Pro forma net loss.....	\$ (7,175,564)	\$ (16,700,952)	\$ (38,500,000)
Basis and diluted net loss per share			
As reported.....	\$ (0.27)	\$ (0.45)	\$ (0.74)
Pro forma.....	\$ (0.34)	\$ (0.74)	\$ (1.48)

The Company's stock option grants vest over several years and the Company intends to grant varying levels of stock options in the future periods. Therefore, the pro forma effects on 2000, 2001, and 2002 net loss and net loss per common share of expensing the estimated fair value of stock options and common shares issued pursuant to the stock option plan are not necessarily representative of the effects on reported results from operations for future years.

(m) Restatement

During 2002, the Company and its previous auditors determined that an error had inadvertently been made in the accounting during 1996 and 1997 for two stock options granted to the Company's former Chief Executive Officer. Due to this error, the accounting treatment did not properly reflect that these options contained a cashless exercise provision. As a result of required non-cash adjustments, the Company's net loss for the year ended December 31, 1996 was understated and the Company's net loss for the year ended December 31, 1997 was overstated. As reflected below, these corrections have no cash impact on the Company and have no impact on Total Shareholders' Equity.

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GENOME THERAPEUTICS CORP. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

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A summary of the cumulative impact of the restatement on the Company's financial statements as of December 31, 2000 and December 31, 2001 is as follows:

	As previously reported	As restated
	-----	-----
December 31, 2000		
Accumulated deficit.....	\$(71,963,333)	\$(81,668,073)
Additional paid in capital	143,018,548	152,723,288
Total shareholders' equity	72,687,452	72,687,452
December 31, 2001		
Accumulated deficit.....	\$(82,053,635)	\$(91,758,375)
Additional paid in capital	146,509,995	156,214,735
Total shareholders' equity	66,731,938	66,731,938

### (2) CASH EQUIVALENTS AND MARKETABLE SECURITIES

The Company applies the provisions of SFAS No. 115, Accounting for Certain Investments in Debt and Equity Securities. At December 31, 2001 and 2002, the Company's investments include short-term and long-term marketable securities, which are classified as held-to-maturity, as the Company has the positive intent and ability to hold these securities to maturity. Cash equivalents are short-term, highly liquid investments with original maturities of 90 days or less. Marketable securities are investment securities with original maturities of greater than 90 days. Cash equivalents are carried at cost, which approximates market value, and consist of debt securities. Marketable securities that are classified as held to maturity are recorded at amortized cost, which approximates market value and consist of commercial paper and U.S. government debt securities. The average maturity of the Company's investments is approximately 6.5 months at December 31, 2002. At December 31, 2002, the Company had an unrealized gain of approximately \$99,000, which is the difference between the amortized cost and the market value of the held to maturity investments.

At December 31, 2002, the Company's short-term marketable securities also includes 45,000 shares of common stock of Vicuron received in connection with its collaboration agreement with Vicuron dated March 10, 1997. The Company is accounting for the shares in accordance with SFAS No. 115 as "available-for-sale securities" and as a result, the shares are recorded at fair value. The shares are subject to restrictions under the securities regulations and cannot be liquidated until at least March 2003.

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### GENOME THERAPEUTICS CORP. AND SUBSIDIARY

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

At December 31, 2001 and 2002, the Company's cash and cash equivalents and investments consisted of the following:

Gross                      Gross

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	Amortized Cost	Unrealized Gains	Unrealized Loss	Estimated Fair Value
December 31, 2001--Held to Maturity				
Cash and Cash Equivalents:				
Cash.....	\$21,801,201	\$ --	\$ --	\$21,801,201
Debt securities.....	3,004,184		(84)	3,004,100
Total cash and cash equivalents.....	\$24,805,385	\$ --	\$ (84)	\$24,805,301
Investments:				
Short-term marketable securities.....	\$29,961,540	\$221,183	\$ --	\$30,182,723
Long-term marketable securities.....	11,839,045	221,083	--	12,060,128
Total investments.....	\$41,800,585	\$442,266	\$ --	\$42,242,851
December 31, 2001--Available for Sale				
Warrant.....	\$ 535,279	\$ --	\$ --	\$ 535,279
December 31, 2002--Held to Maturity				
Cash and Cash Equivalents:				
Cash.....	\$11,128,507	\$ --	\$ --	\$11,128,507
Debt securities.....	3,100,000	--	--	3,100,000
Total cash and cash equivalents.....	\$14,228,507	\$ --	\$ --	\$14,228,507
Investments:				
Short-term marketable securities.....	\$32,584,384	\$ 89,220	\$ (3,067)	\$32,670,537
Long-term marketable securities.....	3,567,757	14,311	(1,862)	3,580,206
Total investments.....	\$36,152,141	\$103,531	\$ (4,929)	\$36,250,743
December 31, 2002--Available for Sale				
Investment in equity securities.....	\$ 200,160	\$285,390	\$ --	\$ 485,550

The Company also has \$200,000 in restricted cash at December 31, 2001 in connection with certain capital lease obligations (see Note 5).

(3) INCOME TAXES

The Company applies SFAS No. 109, Accounting for Income Taxes, which requires the Company to recognize deferred tax assets and liabilities for expected future tax consequences of events that have been recognized in the financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using the enacted tax rates in effect for the year in which the differences are expected to reverse. SFAS No. 109 requires deferred tax assets and liabilities to be adjusted when the tax rates or other provisions of the income tax laws change.

At December 31, 2002, the Company had net operating loss and tax credit carryforwards of approximately \$120,307,000 and \$9,084,000, respectively, available to reduce federal taxable income and federal income taxes,



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## GENOME THERAPEUTICS CORP. AND SUBSIDIARY

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

respectively, if any. Net operating loss and tax credit 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 the ownership interest of significant shareholders over a three-year period in excess of 50%.

The net operating loss and tax credit carryforwards expire approximately as follows:

Expiration Date	Net Operating Loss Carryforwards	Research Tax Credit Carryforwards	Investment Tax Credit Carryforwards
-----	-----	-----	-----
2003.....	\$ --	\$ --	\$ --
2004.....	--	--	--
2005.....	--	80,000	--
2006.....	1,807,000	208,000	--
2007-2021...	118,500,000	8,759,000	37,000
	-----	-----	-----
	\$120,307,000	\$9,047,000	\$37,000
	=====	=====	=====

The components of the Company's net deferred tax asset at the respective dates are as follows:

	December 31,	
	2001	2002
	-----	-----
Net operating loss carryforwards.....	\$ 37,265,000	\$ 48,448,000
Research and development credits.....	6,605,000	9,047,000
Investment tax credits.....	37,000	37,000
Capitalized research & development costs	--	4,897,000
Depreciation.....	1,435,000	1,459,000
Other temporary differences.....	2,798,000	1,783,000
	-----	-----
Net deferred tax asset.....	48,140,000	65,671,000
Valuation allowance.....	(48,140,000)	(65,671,000)
	-----	-----
	\$ --	\$ --
	=====	=====

The valuation allowance has been provided due to the uncertainty surrounding the realization of the deferred tax assets.

#### (4) COMMITMENTS

##### (a) Lease Commitments

At December 31, 2002, the Company has operating leases for computer equipment and office and laboratory facilities, the last of which expires on

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November 15, 2006. Approximate minimum lease payments and facilities charges under the operating leases at December 31, 2002 are as follows:

Year ending December 31, -----	
2003.....	\$1,100,000
2004.....	1,099,000
2005.....	1,103,000
2006.....	1,067,000
	-----
	\$4,369,000
	=====

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### GENOME THERAPEUTICS CORP. AND SUBSIDIARY

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

Rental expense under these operating leases was approximately \$927,000, \$1,007,000 and \$1,020,000 for the years ended December 31, 2000, 2001 and 2002, respectively.

#### (b) Employment Agreements

The Company has employment agreements with its executive officers and several key employees, which provide for bonuses, as defined, and severance benefits upon termination of employment, as defined.

#### (5) LONG-TERM OBLIGATIONS

On March 5, 2002, the Company sold convertible notes payable to two institutional investors in a private placement transaction, raising \$15 million in gross proceeds. The convertible notes payable may be converted into shares of the Company's common stock at the option of the holder, at a price of \$8.00 per share, subject to certain adjustments. The maturity date of the convertible notes payable is December 31, 2004, provided, that if at any time on or after December 31, 2003, the Company maintains a net cash balance (i.e., cash and cash equivalents less obligations for borrowed money bearing interest) of less than \$35 million, then the holders of the convertible notes payable can require that all or any part of the outstanding principal balance of the convertible notes payable plus all accrued but unpaid interest be repaid. Interest on the convertible notes payable accrues at 6% annually and the interest is payable, in cash or in stock, semi-annually on June 30 and December 31 of each year. As of December 31, 2002, two interest payments on the convertible notes payable had become due and were paid by issuing 494,083 shares of the Company's common stock to the holders of the notes payable, of which 120,986 and 373,107 shares were issued in July 2002 and January 2003, respectively. The investors also received a warrant to purchase up to an aggregate of 487,500 shares of common stock at an exercise price of \$8.00 per share, subject to certain adjustments. The warrant is exercisable at the time the convertible notes payable are converted or if certain other redemptions or repayments of the convertible notes payable occur and will terminate upon the earlier of four years from the date of such conversion or December 31, 2008. The warrant was valued, using the Black-Scholes option pricing model, at approximately \$1,736,000. The amount was

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recorded as a discount to long-term obligations and will be amortized to interest expense over the term of the convertible notes payable. Additionally, the Company is obligated to issue a warrant to purchase up to 100,000 shares of common stock at an exercise price of \$15.00 per share to its placement agent in this transaction. The warrant is exercisable over a three-year term which commenced upon the closing of the notes payable transaction. This warrant was valued, using the Black-Scholes option pricing model, at \$244,000. This amount is included in deferred issuance costs and will be amortized to interest expense over the term of the convertible notes payable. As of December 31, 2002, this warrant has not yet been issued.

In February 2002, the Company entered into an additional line of credit for \$3,500,000, of which \$500,000 was used to refinance a portion of an existing line of credit. This line of credit is payable in twelve consecutive quarterly payments at the prevailing LIBOR rate (2.06% at December 31, 2002) plus 1.50%. The Company is required to maintain certain financial covenants pertaining to minimum cash balances. As of December 31, 2002, \$2.6 million was outstanding under the credit line, and the Company was in compliance with all of the covenants.

In February 2000, the Company entered into an equipment line of credit under which it may finance up to \$4,000,000 of laboratory, computer and office equipment. In December 2000, the Company increased the line of credit by \$2,712,000 to \$6,712,000. The Company, at its discretion, can enter into either operating or capital leases. The borrowings under the operating leases are payable in 24 monthly installments and capital leases are payable in 36 monthly installments. As of December 31, 2002, the Company had approximately \$6,000 outstanding under operating leases and approximately \$1,904,000 outstanding under capital leases. The interest rates under the capital leases range from 7.50% to 10.37%. There are no financial covenants related to this agreement. In March 2003, this debt had been paid off in its entirety and there is no additional borrowing capacity available under this line of credit.

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### GENOME THERAPEUTICS CORP. AND SUBSIDIARY

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

Minimum payments under long-term obligations at December 31, 2002 are as follows:

Year ending December 31, -----	
2003.....	\$ 3,681,041
2004.....	17,527,720
2005.....	292,507
	-----
Total minimum payments.....	21,501,268
Less--Discount to long-term obligation.....	1,225,454
Amount representing interest.....	1,997,536
	-----
Present value of total minimum payments.....	18,278,278
Less--Current portion.....	2,623,986
	-----
	\$15,654,292

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(6) SHAREHOLDERS' EQUITY

(a) Stock Options

The Company has granted stock options to key employees and consultants under its 1991, 1993, 1995 and 1997 Stock Option Plans, as well as the 2001 Incentive Plan. The Stock Option and Compensation Committee of the Board of Directors determines the purchase price and vesting schedule applicable to each option grant. In addition, under separate agreements not covered by any plan, the Company has granted certain key employees and directors of the Company, options to purchase common stock.

The Company granted nonqualified stock options for the purchase of 65,000 and 10,000 shares of common stock to consultants during fiscal years 1997 and 1999, respectively. The options were granted with an exercise price equal to the fair market value price at the date of grant and vest ratably over the contract period, as defined. In accordance with Emerging Issues Task Force (EITF) No. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services, the Company will measure the fair value of the options as they vest using the Black-Scholes option pricing model. The Company has charged \$281,636, \$3,160 and \$0 to operations for the years ended December 31, 2000, 2001 and 2002, respectively, related to the grant of these options.

During 1999, the Company granted to certain employees the right to receive 154,616 shares of common stock. The employees received the common stock in two equal installments on the anniversary of the grant date. The Company recorded deferred compensation of \$647,942 related to the grant of these rights to receive the common stock, which will be amortized to expense over the period the shares are earned. Since the inception of this program, employees who resigned from the Company forfeited 62,915 shares of the restricted stock.

The Company records deferred compensation when stock options, restricted stock and other stock-based awards are granted at an exercise price per share that is less than the fair market value on the date of the grant. Deferred compensation is recorded in an amount equal to the excess of the fair market value per share over the exercise price times the number of options or shares granted. Deferred compensation is amortized over the vesting period of the underlying awards. During the years ended 2000, 2001 and 2002, the Company recorded \$1,377,161, \$647,942 and \$300,740, respectively, of deferred compensation. The Company recorded amortization of deferred compensation of approximately \$1,436,660, \$883,983 and \$430,338 for the years ended December 31, 2000, 2001 and 2002, respectively. During 2000 and 2001, in connection with the termination of several employees, the Company reversed \$461,783 and \$17,500, respectively, of unamortized deferred compensation due to the forfeiture of options.

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GENOME THERAPEUTICS CORP. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

There were 1,571,240 common shares available for future grant at December 31, 2002. The following is a summary of all stock option activity:

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	Number of Shares	Exercise Price Range	Weighted Average Price
Outstanding, December 31, 1999	3,639,358	0.00-14.50	3.45
Granted.....	1,198,004	0.00-66.00	14.89
Exercised.....	(1,280,612)	0.00-14.72	2.59
Cancelled.....	(381,769)	0.00-66.00	4.44
Outstanding, December 31, 2000	3,174,981	0.00-66.00	7.99
Granted.....	865,640	1.80-16.08	7.87
Exercised.....	(251,354)	0.00-14.72	3.03
Cancelled.....	(143,403)	0.00-39.38	11.74
Outstanding, December 31, 2001	3,645,864	\$0.00-66.00	\$ 8.15
Granted.....	1,363,746	0.83-7.03	2.43
Exercised.....	(10,614)	0.00-4.42	1.23
Cancelled.....	(522,469)	0.10-48.25	7.72
Outstanding, December 31, 2002	4,476,527	\$0.10-66.00	\$ 6.47
Exercisable, December 31, 2002	2,238,018	\$0.10-66.00	\$ 6.72
Exercisable, December 31, 2001	1,951,126	\$0.10-66.00	\$ 5.73
Exercisable, December 31, 2000	1,607,085	\$0.00-14.72	\$ 4.10

The range of exercise prices for options outstanding and options exercisable at December 31, 2002 are as follows:

Range of Exercise Prices	Weighted Average Remaining Contractual Life of Options Outstanding (In Years)	Options Outstanding		Options Exercisable	
		Number	Weighted Average Exercise Price	Number	Weighted Average Exercise Price
\$ 0.00- 3.38	5.90	1,920,017	\$ 1.64	904,754	\$ 1.86
\$ 3.40- 4.88	7.07	433,112	4.30	328,165	4.37
\$ 5.05- 7.50	8.27	533,543	6.41	133,152	6.80
\$ 7.56- 9.50	4.48	415,874	8.71	330,313	8.82
\$ 9.93-14.72	7.96	1,089,231	13.74	498,752	14.28
\$15.97-66.00	7.54	84,750	22.82	42,882	22.88
Total	6.70	4,476,527	\$ 6.47	2,238,018	\$ 6.72

(b) Sale of Common Stock

In June and July of 2000, the Company sold 1,500,000 shares of its common stock in a series of transactions through the Nasdaq National Market at an average price of \$31.01 per share resulting in proceeds of \$44,722,729, net of issuance costs of \$718,066.

In June and July of 2001, the Company sold 127,500 shares of its common stock in a series of transactions through the Nasdaq National Market at an

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average price of \$13.73 per share resulting in proceeds of \$1,705,767, net of issuance costs of \$44,622.

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### GENOME THERAPEUTICS CORP. AND SUBSIDIARY

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

##### (c) 1997 Directors' Deferred Stock Plan

In January 1998, the Company's stockholders approved the 1997 Directors' Deferred Stock Plan (the 1997 Directors' Plan) covering 150,000 shares of common stock. The shares will be granted as services are performed by members of the Company's Board of Directors. As of December 31, 2002, the Company granted 66,002 shares of restricted common stock under the 1997 Directors' Plan. These shares are issued at the end of the three-year period or earlier if the individual ceases to serve as a member of the Company's Board of Directors. As of December 31, 2002, 25,702 shares of restricted common stock were vested but not yet issued under the 1997 Directors' Plan.

##### (d) Note Receivable from Officer

On March 28, 2001, the Company loaned \$163,000 to an officer of the Company to allow him to pay income tax liabilities associated with a restricted stock grant of 24,000 shares. The loan bears interest at 4% and is payable in full on December 31, 2004 and may be extended to December 31, 2006 at the option of the officer, subject to certain conditions. The principal amount of the note is non-recourse as it is secured only by the 24,000 shares of restricted stock. The interest portion of the loan is full-recourse as it is secured by the officer's personal assets. The Company issued these shares to the officer for no consideration and as a result recorded deferred compensation of approximately \$347,000, which will be amortized over the vesting period of the award, which is forty-eight months.

##### (e) Employee Stock Purchase Plan

On February 28, 2000, the Company adopted an Employee Stock Purchase Plan under which eligible employees may contribute up to 15% of their earnings toward the semi-annual purchase of the Company's common stock. The employees' purchase price will be 85% of the fair market value of the common stock at the time of grant of option or the time at which the option is deemed exercised, whichever is less. No compensation expense will be recorded in connection with the plan. As of December 31, 2002, the Company has issued 226,389 shares under this plan.

##### (7) INCENTIVE SAVINGS 401(K) PLAN

The Company maintains an incentive savings 401(k) plan (the Plan) for the benefit of all employees. In February 2002, the Company changed its match to 50% of the first 6% of salary from 100% of the first 2% of salary and 50% of the next 2% of salary, limited to the first \$100,000 of annual salary. The Company contributed \$201,759, \$251,157 and \$283,718 to the Plan for the years ended December 31, 2000, 2001 and 2002, respectively.

##### (8) ALLIANCES--BIOPHARMACEUTICAL

###### (a) ASTRAZENECA

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

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### GENOME THERAPEUTICS CORP. AND SUBSIDIARY

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

Under this agreement, Astra agreed to pay the Company, subject to the achievement of certain product development milestones, up to \$23.3 million (and possibly a greater amount if more than one product is developed under the agreement) in license fees, expense allowances, research funding and milestone payments. The Company has received a total of \$13.7 million in license fees, expense allowances, milestone payments, maintenance fees and research funding under the Astra agreement through December 31, 2002.

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

The Company recognized approximately \$6,000, \$0 and \$172,000 in revenue under the agreement during the years ended December 31, 2000, 2001 and 2002, respectively.

#### (b) SCHERING-PLOUGH

In December 1995, the Company entered into a strategic alliance and license agreement (the December 1995 agreement) with Schering Corporation and Schering-Plough Ltd. (collectively, Schering-Plough) providing for the use by Schering-Plough of the genomic sequence of *Staph. aureus* to identify and validate new gene targets for development of drugs to target *Staph. aureus* and other pathogens that have become resistant to current antibiotics. As part of this agreement, the Company granted Schering-Plough exclusive access to the Company's proprietary *Staph. aureus* genomic sequence database. The Company agreed to undertake certain research efforts to identify bacteria-specific genes essential to microbial survival and to develop biological assays to be used by Schering-Plough in screening natural product and compound libraries to identify antibiotics with new mechanisms of action.

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

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payments through December 31, 2002. Subject to the achievement of additional product development milestones, Schering-Plough agreed to pay the Company up to an additional \$24.0 million in milestone payments.

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

Under the December 1995 agreement, the Company recognized approximately \$1,887,000, \$1,570,000 and \$127,000 in revenue during the years ended December 31, 2000, 2001 and 2002, respectively.

In December 1996, the Company entered into its second strategic alliance and license agreement (the December 1996 agreement) with Schering-Plough. This agreement calls for the use of genomics to discover new

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### GENOME THERAPEUTICS CORP. AND SUBSIDIARY

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

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

Under this agreement (and subsequent extensions), Schering-Plough paid an initial license fee and an expense allowance to the Company and funded the research program through December 2002. In addition, upon completion of certain scientific developments, Schering-Plough has made or will potentially make milestone payments, as well as pay royalties based upon sales of therapeutic products developed from this collaboration. If all milestones are met, total payments to the Company will approximate \$81.0 million, excluding royalties. Of the total potential payments, approximately \$36.5 million represents license fees and research payments, and \$44.5 million represents milestone payments based on achievement of research and product development milestones. In December 2002, the Company had completed its research obligations under this alliance and the research program has advanced into high-throughput screening at Schering-Plough. A total of \$42.4 million has been received through December 31, 2002.

Under the December 1996 agreement, the Company recognized approximately \$4,711,000, \$8,084,000 and \$5,088,000 in revenue during the years ended December 31, 2000, 2001 and 2002, respectively.

In September 1997, the Company entered into a third strategic alliance and license agreement (the September 1997 agreement) with Schering-Plough to use



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genomics to discover and develop new pharmaceutical products to treat fungal infections. Under this agreement, the Company employed its bioinformatics, high-throughput sequencing and functional genomics capabilities to identify and validate genes and associated proteins as drug discovery targets that can be utilized by Schering-Plough to develop novel antifungal treatments. Schering-Plough has received exclusive access to the genomic information developed in the alliance related to two fungal pathogens, *Candida albicans* and *Aspergillus fumigatus*. Schering-Plough has also received exclusive worldwide rights to make, use and sell products based on the technology developed during the course of the research program. In return, Schering-Plough agreed to fund a research program through March 31, 2002. If all milestones are met, total payments to the Company will approximate \$33.2 million, excluding royalties. Of the total potential payments, approximately \$10.2 million represents contract research payments and \$23.0 million represents milestone payments based on achievement of research and product development milestones. The Company has completed its research obligations under this alliance and has turned over validated drug targets and assays to Schering-Plough for high-throughput screening. A total of \$12.2 million has been received through December 31, 2002.

Under the September 1997 agreement, the Company recognized approximately \$1,912,000, \$1,137,000 and \$6,000 in revenue for the years ended December 31, 2000, 2001 and 2002, respectively.

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

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### GENOME THERAPEUTICS CORP. AND SUBSIDIARY

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

##### (c) BIOMERIEUX

In September 1999, the Company entered into a strategic alliance with bioMerieux to develop, manufacture and sell in vitro diagnostic products for human clinical and industrial applications. As part of the alliance, bioMerieux purchased a subscription to the Company's PathoGenome(TM) Database (see Note 9), paid an up-front license fee, agreed to fund a research program for at least four years and pay royalties on future products. In addition, bioMerieux purchased \$3.75 million of the Company's common stock. The total amount of research and development funding, excluding subscription fees, approximates \$5.2 million for the four-year term of this agreement. The research and development funding will be recognized as the research services are performed over the four-year term of the agreement. Approximately \$4.4 million has been received through December 31, 2002.

The Company recognized approximately \$1,469,000, \$1,173,000 and \$1,188,000 in revenue during the years ended December 31, 2000, 2001 and 2002, respectively, which consisted of alliance research revenue and amortization of the up-front license fees.

##### (d) WYETH

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

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the characterization of a gene associated with a unique high bone mass trait.

The agreement provides for the Company to employ its established capabilities in positional cloning, bioinformatics and functional genomics in conjunction with Wyeth's drug discovery capabilities and its expertise in bone biology and the osteoporotic disease process to develop new pharmaceuticals. Under the terms of the agreement, Wyeth agreed to pay an up-front license fee, milestone payments and fund a research program for a minimum of two years with an option to extend. On December 30, 2002, Wyeth exercised its option to extend the research program to December 2003. If the research program continues for its full term and substantially all of the milestone payments are met, total payments to the Company, excluding royalties, would exceed \$119 million. Approximately \$9.2 million has been received through December 31, 2002.

The Company recognized approximately \$1,640,000, \$6,485,000 and \$1,060,000 in revenue during the years ended December 31, 2000, 2001 and 2002, respectively, which consisted of alliance research revenue, amortization of the up-front license fees and milestone payments.

### (e) AMGEN

In December 2002, the Company entered into a strategic alliance with Amgen, Inc. to identify and develop novel therapeutic agents for bone diseases, including osteoporosis. Both companies will participate in collaborative research efforts to discover one or more drug candidates suitable for development. The companies will, as part of the research activities, use genetic information, developed by the Company based on research conducted at the Creighton University Osteoporosis Research Center, which has been exclusively licensed to Amgen.

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

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## GENOME THERAPEUTICS CORP. AND SUBSIDIARY

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

The Company will receive royalties on product sales ranging from 4%-10% depending on the level of those sales. We may elect to participate in the funding of the clinical development program, in which case we may co-promote the product in the U.S. and Canada and receive either increased royalties on sales or participate in profits from product sales in the U.S. and Canada. The Company recognized approximately \$42,000 in revenue during the year ended December 31, 2002, which consisted of amortization of an up-front license fee.

### (9) GENOMEVISION(TM) SERVICES

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GenomeVision(TM) Services revenues consist of government grants, fees received from custom gene sequencing and analysis and subscription fees from PathoGenome(TM) Database. (See Note 13)

### (a) DATABASE SUBSCRIPTIONS

The Company has entered into a number of PathoGenome(TM) Database subscriptions. The database subscriptions provide nonexclusive access to the Company's proprietary genome sequence database, PathoGenome(TM) Database, and associated information relating to microbial organisms. These agreements call for the Company to provide periodic data updates, analysis tools and software support. Under the subscription agreements, the customer pays an annual subscription fee and will pay royalties on any molecules developed as a result of access to the information provided by the PathoGenome(TM) Database. The Company retains all rights associated with protein therapeutic, diagnostic and vaccine use of bacterial genes or gene products. In 2001, we entered into an agreement with EraGen Biosciences, under which they are responsible for the marketing, distribution and maintenance of this product, while we retain our rights to use it and receive a percentage of subscription fees and royalties from subscriber discoveries.

### (b) NATIONAL HUMAN GENOME RESEARCH INSTITUTE

In July 1999, the Company was named as one of the nationally funded DNA sequencing centers of the international Human Genome Project. The Company is entitled to receive funding from the National Human Genome Research Institute (NHGRI) of up to \$18.4 million through June 2003, of which all funds have been appropriated. As of December 31, 2002, the Company recognized approximately \$17.4 million in revenue under this agreement.

In October 1999, the NHGRI named the Company as a pilot center to the Mouse Genome Sequencing Network. The Company is entitled to receive \$14.8 million in funding through February 2003, of which all funds have been appropriated. As of December 31, 2002, the Company recognized approximately \$14.7 million in revenue under this agreement. In August 2000, the Company was named one of two primary centers for the Rat Sequencing Program from NHGRI. As part of the agreement, the Company 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.

### (10) PRODUCT DEVELOPMENT

In October 2001, the Company acquired an exclusive license in the United States and Canada for a novel antibiotic, Ramoplanin, from Biosearch Italia S.p.A (which merged with Versicor in March 2003 and subsequently changed its name to Vicuron). The Company has assumed responsibility for the product development in the United States of Ramoplanin, currently in a Phase III clinical trial for the prevention of bloodstream infections caused by vancomycin-resistant enterococci (VRE), as well as a Phase II clinical trial to assess the safety and efficacy of Ramoplanin to treat Clostridium difficile-associated diarrhea (CDAD). The agreement provides the Company with exclusive rights to develop and market oral Ramoplanin in the U.S. and Canada. Vicuron will provide the bulk material for manufacture of the product and will retain all other rights to market and sell Ramoplanin.

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## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

Under the terms of this agreement, the Company paid Vicuron an initial license fee of \$2 million and is obligated to make payments of up to \$8 million in a combination of cash and notes convertible into Company stock upon the achievement of specified milestones. In addition, the Company is obligated to purchase bulk material from Vicuron, fund the completion of clinical trials and pay a royalty on product sales. The combined total of bulk product purchases and royalties is expected to be approximately 26% of the Company's net product sales.

The Company expended approximately \$5,549,000 and \$13,895,000 during the years ended December 31, 2001 and 2002, respectively, which consisted of the initial license fee, milestone payment and clinical development expenses.

### (11) QUARTERLY RESULTS OF OPERATIONS

The following table sets forth unaudited quarterly statement of operations data for each of the eight quarters in the period ended December 31, 2002. In the opinion of management, this information has been prepared on the same basis as the audited financial statements appearing elsewhere in this Form 10-K, and all necessary adjustments, consisting only of normal recurring adjustments, have been included in the amounts stated below to present fairly the unaudited quarterly results of operations.

	Quarter One	Quarter Two	Quarter Three	Quarter Four	
	-----	-----	-----	-----	
2001					
Revenues:					
Biopharmaceutical.....	\$ 3,557,570	\$ 7,459,478	\$ 2,917,389	\$ 4,503,849	\$
GenomeVision(TM) Services.....	4,532,678	3,930,400	4,460,646	4,378,514	
	-----	-----	-----	-----	-----
Total revenues.....	8,090,248	11,389,879	7,378,035	8,882,363	
Costs and Expenses:					
Cost of services.....	3,680,816	3,430,803	4,633,058	4,408,030	
Research and development.....	3,822,329	4,438,822	5,247,912	10,548,697	
Selling, general and administrative...	1,634,922	2,190,432	2,559,004	2,382,871	
	-----	-----	-----	-----	-----
Total costs and expenses.....	9,138,067	10,060,057	12,439,974	17,339,598	
	-----	-----	-----	-----	-----
Loss from operations.....	(1,047,819)	1,329,822	(5,061,939)	(8,457,235)	(
Interest Income (Expense):					
Interest income.....	1,143,795	986,723	1,055,631	653,111	
Interest expense.....	(169,342)	(212,123)	(174,269)	(136,657)	
	-----	-----	-----	-----	-----
Net interest income.....	974,453	774,600	881,362	516,454	
	-----	-----	-----	-----	-----
Net loss.....	\$ (73,366)	\$ 2,104,422	\$ (4,180,577)	\$ (7,940,781)	\$ (
	=====	=====	=====	=====	=====
Net Loss per Common Share:					
Basic and diluted.....	\$ (0.00)	\$ 0.09	\$ (0.18)	\$ (0.35)	\$
	=====	=====	=====	=====	=====
Weighted Average Common Shares					
Outstanding:					
Basic and diluted.....	22,409,501	22,451,753	22,685,660	22,742,794	
	=====	=====	=====	=====	=====

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GENOME THERAPEUTICS CORP. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

	Quarter One	Quarter Two	Quarter Three	Quarter Four
2002				
Revenues:				
Biopharmaceutical.....	\$ 2,433,725	\$ 1,927,960	\$ 1,844,312	\$ 1,509,995
GenomeVision(TM) Services.....	3,730,792	4,056,708	3,155,353	4,328,010
Total revenues.....	6,164,517	5,984,668	4,999,665	5,838,005
Costs and Expenses:				
Cost of services.....	3,392,777	3,696,543	3,074,407	5,255,709
Research and development.....	7,813,973	8,283,727	9,211,517	7,125,869
Selling, general and administrative...	2,057,385	2,188,430	2,629,129	2,506,987
Total costs and expenses.....	13,264,135	14,168,700	14,915,053	14,488,565
Loss from operations.....	(7,099,618)	(8,184,032)	(9,915,388)	(8,650,560)
Interest Income (Expense):				
Interest income.....	530,932	494,671	400,636	342,451
Interest expense.....	(216,090)	(628,126)	(557,865)	(534,036)
Net interest income (expense).....	314,842	(133,455)	(157,229)	(191,585)
Net loss.....	\$ (6,784,776)	\$ (8,317,487)	\$ (10,072,617)	\$ (8,842,145)
Net Loss per Common Share:				
Basic and diluted.....	\$ (0.30)	\$ (0.36)	\$ (0.44)	\$ (0.38)
Weighted Average Common Shares				
Outstanding:				
Basic and diluted.....	22,798,224	22,812,226	23,032,463	23,040,590

(12) ACCRUED EXPENSES

Accrued expenses consist of the following:

	December 31,	
	2001	2002
Payroll and related expenses.....	\$1,990,394	\$2,278,679
Facilities.....	463,279	368,601
Professional fees.....	108,375	180,000
Employee relocation.....	224,543	--
Interest related to convertible notes payable	--	453,699

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Clinical development.....	1,286,324	4,329,792
All Other.....	759,798	798,169
	-----	-----
	\$4,832,713	\$8,408,940
	=====	=====

(13) SUBSEQUENT EVENT

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

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GENOME THERAPEUTICS CORP. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

As discussed above, the Company will receive royalties on gene sequencing revenue earned by Agencourt that is related to the transferred business for a period of two years after the date of sale. Accordingly, the cash flows from the GenomeVision(TM) Services group will not have been completely eliminated from the ongoing operations of the Company as a result of the disposal transaction. As a result, the sale does not initially qualify as a "discontinued operation" as defined by SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets."

In connection with the sale of its GenomeVision(TM) Services business, the Company determined that certain equipment related to this segment will no longer be used and will be abandoned subsequent to the sale. As a result, the Company revised the estimated useful lives of this equipment and recorded additional depreciation expense of \$669,000 during the fourth quarter of 2002. The Company also evaluated and wrote down its excess inventory of disposables related to the GenomeVision(TM) Services business by \$312,000 during the fourth quarter of 2002. Additionally, through this divestiture, the Company eliminated approximately 60 full-time positions, of which approximately 49 employees were not offered employment with Agencourt. The Company will record and pay severance costs of approximately \$636,000 during the first quarter of 2003 related to these employees. Refer to Note 1(j) for certain segment information related to GenomeVision(TM) Services.

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