GENOME THERAPEUTICS CORP
Form 10-K
March 05, 2004

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark one)

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

For the fiscal year ended: December 31, 2003

OR

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

Commission file number: 0-10824

GENOME THERAPEUTICS CORP.

(Exact name of registrant as specified in its charter)

Massachusetts	**04-2297484**

(State or other jurisdiction of incorporation or organization)	(IRS employer identification number)
100 Beaver Street, Waltham, Massachusetts **(Address of principal executive offices)**	**02453** **(Zip Code)**

Registrant s telephone number: (781) 398-2300

Securities registered pursuant to Section 12(b) of the Act:

None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, $.10 Par Value

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

Indicate by check mark 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 27, 2003, the last business day of the registrant s most recently completed second fiscal quarter, was approximately $68,969,000.

The number of shares outstanding of the registrant s common stock as of March 3, 2004 was 73,894,560.

Documents Incorporated By Reference. Portions of the registrant s proxy statement for use at its Annual Meeting to be held on April 13, 2004 are incorporated by reference into Part III.

PART I

Item 1. ***Business***

Overview

We are a biopharmaceutical company committed to the clinical development and commercialization of new therapeutics to serve unmet medical needs. On February 6, 2004, we announced the completion of our merger with GeneSoft Pharmaceuticals, Inc. (Genesoft), a privately-held pharmaceutical company based in South San Francisco, California.

Our product portfolio is now led by the FDA-approved fluoroquinolone antibiotic FACTIVE® (gemifloxacin mesylate) tablets, indicated for the treatment of community-acquired pneumonia of mild-to-moderate severity and acute bacterial exacerbations of chronic bronchitis.

In addition, we are developing a novel antibiotic candidate, Ramoplanin, which is currently in clinical trials for the prevention and treatment of serious hospital-acquired infections. Ramoplanin is in a Phase III trial for the prevention of bloodstream infections caused by vancomycin-resistant enterococci and in a Phase II trial for the treatment of *Clostridium difficile*-associated diarrhea.

Our preclinical development programs include an oral peptide deformylase inhibitor series for the potential treatment of respiratory tract infections as well as development of a FACTIVE intravenous formulation. We also have six pharmaceutical alliances focused on the development of novel therapeutics and diagnostics for chronic human diseases and certain infectious diseases. These alliances were formed in previous years based on our genomics drug discovery expertise. Our business strategy has shifted away from gene discovery and partnerships of this type to focus on the development and commercialization of our own products.

Business Strategy

Our strategy is to advance our existing product and clinical candidates while exploring options to supplement our pipeline with additional opportunities, through either in-licensing or acquisition.

Commercial Launch and Further Development of FACTIVE Tablets

Our primary business focus is the launch of FACTIVE tablets in the U.S. for treating community-acquired pneumonia of mild to moderate severity and acute bacterial exacerbations of chronic bronchitis. We are building a sales and marketing infrastructure to support commercialization and plan to pursue additional indications for FACTIVE, as well as new formulations of the product.

Clinical Development of Ramoplanin and Other Assets

We are also committed to the development of our novel antibiotic, Ramoplanin. We are advancing the clinical program of Ramoplanin through a Phase II trial for the treatment of *Clostridium difficile*-associated diarrhea and a Phase III trial for the prevention of bloodstream infections caused by vancomycin-resistant enterococci. Additionally, we are exploring avenues for advancing our preclinical oral peptide deformylase inhibitor program, most likely through a co-development partner.

Potential In-Licensing and Acquisition of Other Products and Product Candidates

As we have done over the past three years, we will continue to explore ways of expanding our existing product portfolio through the licensing and acquisition of complementary products and product candidates.

Pharmaceutical and Diagnostic Programs

We have ten ongoing product development programs. Led by our FDA-approved product, FACTIVE tablets, our portfolio also includes Ramoplanin, 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). Our preclinical pipeline consists of an oral peptide deformylase inhibitor series and a

FACTIVE intravenous formulation program. In addition, we have six alliances with pharmaceutical companies including AstraZeneca, bioMérieux, Schering-Plough and Wyeth. We also plan to supplement our product portfolio by pursuing additional indications and treatment regimens for FACTIVE tablets.

Infectious Diseases Market

Infectious diseases represent the second leading cause of death worldwide accounting for over 14 million deaths each year. Bacterial infections are the sixth leading cause of death in the U.S. Antibacterials represent the largest segment of the anti-infective market, with an estimated $27 billion in total worldwide sales.

The principal structural classes of antibiotics include beta-lactams, quinolones, macrolides, tetracyclines, aminoglycosides, glycopeptides and trimethoprim combinations. Penicillin, a member of the beta-lactam class, which also includes extended-spectrum penicillins, cephalosporins and carbapenems, was first developed in the 1940s. Nalidixic acid, the earliest member of the quinolone class, was discovered in the 1960s. Major advances were made in the 1970s with the development of new beta-lactams and in the 1980s with the development of new quinolones and macrolides.

Bacterial resistance to existing antibiotics has been increasing in recent years, leading to bacterial infection recurrences, treatment failures and higher costs. These factors have fueled a growing need for more effective products in existing antibiotic classes, as well as for products with new mechanisms of action.

Community Respiratory Diseases (FACTIVE Tablets)

Acute Bacterial Exacerbations of Chronic Bronchitis: Chronic bronchitis is a health problem associated with significant morbidity and mortality. It is estimated that chronic bronchitis affects up to 13 million individuals or approximately 4% to 6% of adults in the United States. Patients with chronic bronchitis are prone to frequent exacerbations, characterized by increased cough and other symptoms of respiratory distress. Longitudinal studies have estimated that 1 to 4 exacerbations occur each year in patients with chronic bronchitis, and such exacerbations are estimated to account for approximately 12 million physician visits per year in the U.S. Antibiotic therapy, the standard treatment for acute bacterial exacerbations of chronic bronchitis, or ABECB, is typically effective in reducing the course of illness for patients.

Community-Acquired Pneumonia: Community-acquired pneumonia, or CAP, is a common and serious illness in the United States. The 3 to 4 million reported cases per year of CAP result in approximately 10 million physician visits, 1 million hospitalizations, approximately 64 million days of restricted activity and 45,000 deaths annually. Antibiotics are the mainstay of treatment for most patients with pneumonia, and where possible, antibiotic treatment should be specific to the pathogen responsible for the infection and individualized. However, since the responsible pathogen is not identified in a high proportion of patients with CAP, physicians usually take an empiric approach to treatment in the first instances. Over the last decade, resistance to penicillin and macrolides has increased significantly, and in many cases, quinolones are now recommended as a first line of therapy due to their efficacy against a wide range of respiratory pathogens, including many antibiotic resistant strains. The most recent treatment guidelines from the Infectious Diseases Society of America recommend quinolones as a first line treatment for certain higher-risk patients with CAP.

FACTIVE Tablets

As a result of our merger with Genesoft Pharmaceuticals, which was completed in February 2004, we gained rights to market gemifloxacin in North America and most of Europe under the brand name FACTIVE (gemifloxacin mesylate) tablets. Gemifloxacin is a member of the fluoroquinolone class of antibiotics. In April 2003, FACTIVE tablets were approved by the FDA for the treatment of ABECB and CAP of mild to moderate severity. In July 2003, FACTIVE tablets were also approved to treat CAP caused by multi-drug resistant *Streptococcus pneumoniae*, or *S. pneumoniae*, a growing clinical concern. Multi-drug resistant *S. pneumoniae*, or MDRSP, is defined as *S. pneumoniae* resistant to two or more of the following antibiotics: penicillin, second-generation cephalosporins (such as cefuroxime), macrolides, tetracyclines, and trimethoprim/sulfamethoxazole. FACTIVE tablets are the only antimicrobial currently approved for this indication.

FACTIVE tablets have potent *in vitro* activity against a wide range of Gram-positive, Gram-negative and atypical pathogens, including key respiratory pathogens, such as *S. pneumoniae, Haemophilus influenzae* and *Moraxella catarrhalis.* FACTIVE tablets are bactericidal at clinically achievable concentrations. Gemifloxacin, the active ingredient in FACTIVE tablets, targets two enzymes in bacteria and has minimum inhibitory concentrations, or MICs, as low as 0.03 µg/ml for *S. pneumoniae*. FACTIVE tablets have been administered to 6,775 patients and have a good overall safety and tolerability profile comparable to other currently marketed antibiotics. FACTIVE tablets have been the subject of over 200 publications. Among the research published are data indicating the drug s ability to reduce the number of ABECB recurrences over a six-month period following treatment.

Within the antibiotic market, quinolones, a product class with close to $3 billion in annual sales in the U.S. in 2002, have been gaining market share at the expense of older antibiotics, according to IMS Health. This is a trend that is expected to continue as resistance to older antibiotic classes increases. Due to their microbiological activity and clinical efficacy, FACTIVE tablets represent an alternative choice for the treatment of certain respiratory tract infections.

Mechanism of Action: FACTIVE tablets act by inhibiting bacterial DNA synthesis through the inhibition of both DNA gyrase and topoisomerase IV, two enzymes essential for bacterial growth and survival. Strains of *S. pneumoniae* showing mutations in both DNA gyrase and topoisomerase IV (double mutants) are resistant to most fluoroquinolones. Since gemifloxacin has the ability to inhibit both target enzymes at therapeutically relevant drug levels, some of these *S. pneumoniae* double mutants remain susceptible to FACTIVE tablets. FACTIVE tablets are also active against many strains of *S. pneumoniae* that are resistant to other classes of antibiotics. There is no known bacterial cross-resistance between gemifloxacin and any other class of antimicrobials.

Clinical Efficacy: The clinical program for FACTIVE tablets included 14 Phase III trials. FACTIVE tablets were studied for the treatment of acute bacterial exacerbation of chronic bronchitis in three pivotal, double-blind, randomized, active-controlled clinical trials using 320 mg once daily for 5 days. In these non-inferiority studies, a total of 826 patients received treatment with FACTIVE tablets and 822 patients received treatment with an active comparator, namely levofloxacin, clarithromycin or amoxicillin/clavulanate. The primary endpoint was clinical response at follow-up. The results for the principal Phase III ABECB studies demonstrated that FACTIVE tablets given once daily for 5 days were at least as effective as the comparators given for 7 days. The clinical success rates for each of these three trials were as follows:

FACTIVE tablets 5 days (320 mg): 88.2%	Levofloxacin 7 days (500 mg): 85.1%
FACTIVE tablets 5 days (320 mg): 86.0%	Clarithromycin 7 days (500 mg 2 times/day, or bid): 84.8%
FACTIVE tablets 5 days (320 mg): 93.6%	Amoxicillin/clavulanate 7 days (500 mg/125 mg, 3 times/day, or tid): 93.2%

FACTIVE tablets were also studied for the treatment of community-acquired pneumonia in three double-blind, randomized, active-controlled clinical studies, one open, active-controlled study, and two uncontrolled studies. In total, 1,349 patients with CAP were treated with FACTIVE tablets, including 1,037 patients treated for 7 days and 927 patients were treated with an active comparator. The primary endpoint for each of these three trials was clinical response at follow-up.

The results of these studies showed that gemifloxacin was effective in the treatment of mild to moderate CAP. The clinical success rates for FACTIVE tablets in studies with a fixed 7-day duration ranged from 89% to 92%. In the pivotal CAP comparator study, a 7-day treatment regimen of FACTIVE tablets 320 mg once daily was shown to be as effective as a 10-day treatment course of amoxicillin/clavulanate (500 mg/125 mg tid). The clinical success rates for the two treatment arms were:

FACTIVE tablets 7 days (320 mg): 88.7%	Amoxicillin/clavulanate 10 days (500 mg/125 mg tid): 87.6%

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Clinical studies showed that FACTIVE tablets were effective in the treatment of CAP due to penicillin-resistant *S. pneumoniae*, or PRSP. Of 11 patients with PRSP treated with FACTIVE tablets for 7 days, 100% achieved both clinical and bacteriological success at follow-up. FACTIVE tablets are also effective in the treatment of CAP due to MDRSP. In clinical trials, of 22 patients with MDRSP treated with FACTIVE tablets for 7 days, 19 (87%) achieved both clinical and bacteriological success at follow-up. FACTIVE tablets are the first and only antibiotic approved to treat mild to moderate CAP caused by this multi-drug resistant organism.

Potential Competitive Advantages: The potential competitive advantages of FACTIVE tablets include:

- FACTIVE tablets have been shown in *in vitro* studies to be active against many bacterial isolates resistant to other classes of antibiotics, and are the only antibiotic approved to treat community-acquired pneumonia of mild to moderate severity caused by multi-drug resistant *S. pneumoniae.*

- FACTIVE tablets have a dual mechanism of action in bacteria, which targets two enzymes essential for bacterial growth and survival at therapeutically relevant drug levels, and as a result we believe have low *in vitro* potential for resistance generation.

- FACTIVE tablets can be dosed once daily, with short courses of therapy for both ABECB (5 days) and CAP (7 days).

- FACTIVE tablets have patent protection into 2015, longer than any currently marketed fluoroquinolones or other antibiotics widely used to treat respiratory tract infections.

Safety and Tolerability: FACTIVE tablets have been studied in nearly 7,000 patients and have a favorable safety profile. The incidence of adverse events reported for FACTIVE tablets was low and comparable to comparator drugs, namely beta-lactam antibiotics, macrolides and other fluoroquinolones. Most adverse events were described as mild to moderate.

Although rash was more frequent among FACTIVE-treated patients in the total patient population than among those who received comparator drugs, in the adult population most at risk for CAP of mild to moderate severity and ABECB (patients over 40 years of age) and at the approved dosage (320 mg for 7 days or less), the rate of rash with FACTIVE tablets was low and comparable to that seen with other antibiotics.

As a post-marketing study commitment, the FDA has required a prospective, randomized study comparing FACTIVE tablets (5,000 patients) to an active comparator (2,500 patients) in patients with CAP or ABECB. This study will include patients of different ethnicities, to gain safety information in populations not substantially represented in the existing clinical trial program, specifically as it relates to rash. Patients will be evaluated for clinical and microbiological success. This Phase IV trial is expected to commence proximate to the product launch in the U.S.

Additional Development of Gemifloxacin: Clinical trials of FACTIVE tablets for the treatment of acute bacterial sinusitis, or ABS, have also been completed. Two double-blind, randomized, active-controlled clinical studies were conducted to examine the efficacy of FACTIVE 320 mg once daily for 7 days in the treatment of patients with ABS. In these studies, 540 patients received FACTIVE tablets and 536 patients received active comparator, namely trovafloxacin or cefuroxime. The primary endpoint was clinical success at follow-up. The result of these clinical trials showed comparable clinical success for patients treated with FACTIVE tablets and those treated with comparator drugs. In addition, a double-blind, randomized, active-controlled clinical study comparing a FACTIVE 7-day treatment regimen for ABS with a FACTIVE 5-day treatment regimen showed similar efficacy between the two treatment arms. Two open-label studies also support the efficacy of FACTIVE tablets given for 5 days for the treatment of ABS. We anticipate filing a New Drug Application (NDA) for this indication in 2005.

An intravenous formulation of gemifloxacin is also in development. We expect that FACTIVE intravenous will undergo a Phase I bioequivalence study in the coming months. Pending a successful outcome of the first study, we plan to conduct a single Phase III trial of the intravenous formulation before pursuing market approval from the FDA. We are currently reviewing a strategy for filing for regulatory approval of FACTIVE tablets in the European Union and anticipate that these filings could be made as early as 2006.

License Agreement: We license the rights to gemifloxacin, the active ingredient in FACTIVE tablets, from LG Life Sciences of the Republic of Korea. We have the rights to commercialize gemifloxacin in North America, France, Germany, the United Kingdom, Luxembourg, Ireland, Italy, Spain, Portugal, Belgium, the Netherlands, Austria, Greece, Sweden, Denmark, Finland, Norway, Iceland, Switzerland, Andorra, Monaco, San Marino and Vatican City. The term of the agreement extends at least through gemifloxacin s patent life which currently expires in 2015 with respect to the principal patents for gemifloxacin, and the term could extend further depending upon several factors, including whether we obtain patent extensions and the timing of our commercial sale of the product in a particular country. The agreement also requires a minimum sales commitment over a period of time, which if not met, would result in the technology being returned to LG Life Sciences. Under this agreement, we are responsible, at our expense and through consultation with LG Life Sciences, for the clinical and commercial development of gemifloxacin in the countries covered by the license, including the conduct of clinical trials, the filing of drug approval applications with the FDA and other applicable regulatory authorities and the marketing, distribution and sale of gemifloxacin in our territory; provided, that LG Life Sciences has the right to co-promote the product, on terms to be negotiated, in our territory for 2008 and periods commencing thereafter, in which case our royalty obligations to LG Life Sciences would cease. The agreement also provides LG Life Sciences with the right to negotiate with us for 180 days to obtain rights to develop our DNA Nanobinder compounds in East Asia for certain skin disorders following the completion of a Phase II clinical trial for such a compound.

Under our license agreement, we were required to pay LG Life Sciences $8 million upon the completion of the merger with Genesoft and will have to make additional payments when specific commercialization milestones are achieved. In addition, per our agreement with LG Life Sciences, we have made the first half of a $4.8 million payment for the purchase of the drug inventory. The arrangement also provides for potential additional milestone payments to LG Life Sciences of up to $22 million, primarily upon achieving sales targets. We are required to buy bulk drug requirements from LG Life Sciences (see Manufacturing below), and will pay LG Life Sciences a royalty on sales in the U.S. and the territories covered by the license in Europe. The gross margin on product sales, including royalty obligations, is projected to be approximately 75% during the first two years, and in the 65 to 70% range after those periods.

Hospital-Acquired Infections (Ramoplanin)

Clostridium difficile-Associated Diarrhea (CDAD): CDAD, a serious form of colitis caused by toxins produced by the Gram-positive bacterium *Clostridium difficile* (*C. difficile*), is the most common form of antibiotic-associated diarrhea in the hospital setting. 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 vancomycin-resistant enterococci (VRE). Resistance has been reported for both drugs.

Enterococcal Bloodstream Infections: Enterococci are a family of Gram-positive bacteria that are part of the normal flora of the human gastrointestinal, or 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 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 the bloodstream infections it causes, 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-susceptible 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 measures to date have focused on screening for colonized patients and using 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 date to prevent VRE bloodstream infections by decolonization have been unsuccessful, according to an article in *The New England Journal of Medicine*. Bacitracin has been tried in combination with or without gentamicin or a tetracycline. Novobiocin has also been tried. It is believed that these approaches have not been successful due to lack of potency or the inability of the antibacterials to reach sufficient levels in the gut to suppress VRE effectively.

Ramoplanin

In October 2001, we in-licensed Ramoplanin from 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 that may make it a particularly attractive compound for killing bacteria in the GI tract. As a result, we are studying the product candidate for the treatment of certain infections (such as *C. difficile*) that occur in the GI tract as well as 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.

Clinical Trials: In a Phase II, multicenter, double-blind, placebo-controlled trial examining suppression of GI VRE colonization, 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

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the placebo patients had detectable VRE (p=0.01). Subsequently, the ongoing Phase III study was designed to demonstrate whether oral Ramoplanin reduced the incidence of VRE bloodstream infections in cancer patients carrying VRE bacteria in their intestines. Ramoplanin has been granted Fast Track status by the FDA for this indication. This trial is on-going. 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 60% of the projected 65 events (bloodstream infections caused by VRE) required for completion have been recorded. 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.

In 2003, 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 are administered for ten days, during which data on Ramoplanin is being 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 both *in vitro* and *in vivo* (hamster model) activity against *C. difficile,* including strains resistant to metronidazole and vancomycin. The clinical development program of Ramoplanin for the potential treatment of CDAD received Fast Track status from the FDA in February 2004. We currently expect to announce initial results for the Phase II trial of Ramoplanin for CDAD in the first half of 2004 and, assuming successful completion of this trial, commence the Phase III CDAD program before the end of 2004. Based on these development plans, we anticipate that we will file an NDA for the CDAD indication prior to filing one for the VRE bloodstream prevention claim.

Potential Competitive Advantages: The potential competitive advantages of Ramoplanin include:

- Ramoplanin is from a novel class of antibiotics and there have been no observed cases of bacterial resistance or cross-resistance with other antibiotics.
- Ramoplanin is orally administered, but not absorbed into the bloodstream, so it concentrates and exerts its killing effects in the GI tract.
- Its bactericidal effect may result in lower potential for bacteria to develop resistance.
- Ramoplanin has a Gram-positive spectrum of activity and low potency against Gram-negative anaerobes making it less likely that its use will result in the overgrowth of other opportunistic organisms.
- There are currently no products, to our knowledge, addressing the critical need for preventing VRE bloodstream infections.

License Agreement: Our license agreement with Vicuron provides us with exclusive rights to develop and market oral Ramoplanin in the U.S. and Canada. Under this agreement, we are responsible, at our expense, for the clinical and non-clinical development of Ramoplanin in our field, the prevention and treatment of human disease, in the United States and Canada, including the conduct of clinical trials and the filing of drug approval applications with the FDA and other applicable regulatory authorities. Vicuron is responsible for providing us with all information in its possession relating to Ramoplanin in our licensed field and for cooperating with us in obtaining regulatory approvals of Ramoplanin. We are obligated to purchase and Vicuron is obligated to provide 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 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.

Drug Discovery Alliances

In the past, it was our business strategy to form strategic alliances with major pharmaceutical companies to discover, develop and commercialize products based on our gene discoveries. While we have shifted our focus away from forming alliances of this type and have discontinued our gene discovery activities, our six existing pharmaceutical alliances still have the potential to deliver value in the future.

Bacterial and Fungal Infection Alliances

Ulcers: Approximately two-thirds of the world s population is infected with *H. pylori* and 25 million Americans suffer from peptic ulcer disease at some point in their life. Worldwide sales of anti-ulcerants were $17.4 billion in 2000.

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. It is estimated that those infected with H. pylori have a two to six fold increased likelihood of developing stomach cancer. 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* may 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® and Prilosec®, generated worldwide sales of $6.0 billion in 2003. As of December 31, 2003, we had received payments of $13.7 million under this alliance and have rights to receive, based on attainment of milestones, an additional $9.8 million of payments in addition to potential royalties. In August 1999, we completed our research obligations under this alliance and turned over validated drug targets and assays to AstraZeneca for preclinical testing. AstraZeneca announced in 2002 that it had begun optimization on a lead series identified through the high-throughput screening program conducted using one of these targets. On March 31, 2003, AstraZeneca s exclusive access rights to our *H. pylori* genomic sequence technology terminated.

Drug-Resistant Bacterial Infections: The pathogen *Staphylococcus aureus* (*S. aureus*) is a common cause of skin, wound and blood infections. *S. aureus* infections are typically treated with antibiotics. In recent decades, the incidence of *S. 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 *S. aureus*. We believe that drugs targeted at genes essential to the survival of *S. aureus* may 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 *S. 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, 2003, 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 are of concern 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 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 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 may represent 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® and Tinactin® lines of topical antifungals. As of December 31, 2003, 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 diseases, including the identification of new pathogens, the re-emergence of old infectious agents and the rapid development 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 $28.5 billion *in vitro* diagnostic global market.

In September 1999, we entered into a strategic alliance with bioMérieux to develop, manufacture and sell *in vitro* pathogen diagnostics for human clinical and industrial applications. A privately held company based in France, bioMérieux is one of the top 10 diagnostics companies in the world and a leader in the field of microbiology. The total amount of research and development funding provided by bioMérieux approximated $5.2 million for the four-year term of the agreement, which concluded on December 31, 2003. As of December 31, 2003, we had received payments of $5.2 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 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 may 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. As of December 31, 2003, we had received payments of $10.3 million under this alliance and have rights to receive, subject to the achievement of milestones, an additional $108.7 million in milestone payments and research support, as well as royalties on sales of any products developed. This program entered high-throughput screening for drug candidates in 2002. As of December 31, 2003, we had completed our research requirements under this agreement.

Asthma: Asthma affects between 100 and 150 million people worldwide according to the World Health Organization and the incidence of asthma appears to be rising dramatically. In the United States, asthma now affects approximately 4% to 10% of the United States population.

The annual direct and indirect costs associated

with treating the disease close to $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 Clarinex® and the Claritin® line of antihistamines; Schering-Plough s allergy and respiratory franchise reported sales of $2.4 billion in 2003. As of December 31, 2003, we had received payments of $42.5 million under this alliance and have rights to receive, based on attainment of milestones, an additional $38.5 million of payments as well as potential royalties. Under this alliance, 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 and the program is now in high-throughput screening for drug candidates.

Bone Diseases: On January 9, 2004, we announced the completion of our research alliance with Amgen for the identification and development of novel therapeutic agents for bone diseases, including osteoporosis. During the collaboration, we discovered a novel gene linked to high bone mass. Upon termination, we regained intellectual property rights to the program and the gene discovery. We received $4.7 million in revenue associated with this alliance during the year ended December 31, 2003.

Internal Drug Discovery

Bacterial Infections

Our current portfolio of internal drug discovery programs focuses on bacterial infections and the growing need to develop antibacterial compounds with novel mechanisms of action.

Peptide Deformylase Inhibitors: In August 2002, Genesoft entered into a research and license agreement with British Biotech Pharmaceuticals Ltd., now Vernalis, to co-develop inhibitors of peptide deformylase, or PDF, a novel iron-binding enzyme essential for bacterial growth but not involved in human cytoplasmic protein synthesis. Genome Therapeutics believes that PDF inhibitors represent an excellent opportunity for the development of novel mode of action antibiotics.

Preclinical studies of our first-generation PDF inhibitor indicated that the compound may have potential for the treatment of hospitalized patients suffering from CAP. An intravenous formulation of this compound entered Phase I clinical trials in October 2002. The drug candidate was well tolerated and demonstrated good pharmacokinetic properties, but did not have an ideal spectrum of activity against common respiratory pathogens. Our research program is now focused on the optimization of second-generation, orally-available PDF inhibitors with the potential to target the broader community-based antibiotic market. Several compounds have been identified with improved properties, including good activity against *H. influenzae.* With continued success, we anticipate selecting a development candidate and initiating IND-enabling studies.

Novel Anti-Infective Series: As a result of our internal drug discovery efforts, we have identified two novel chemical series ready to enter the lead optimization phase with a partner. These two lead series are aimed at novel, broad-spectrum targets and have the potential to be new classes of antibacterials. In addition to these lead compounds, we have identified hit series on six additional antimicrobial screens.

Genomics Services

As part of our continued evolution into a focused biopharmaceutical company, in March 2003 we sold our genomics services business to privately held Agencourt Bioscience Corporation (Agencourt). As part of the agreement, we transferred our sequencing operations, including certain equipment and personnel to Agencourt. We received an upfront cash payment of $200,000 and shares of Agencourt common stock and we will receive a percentage of revenues from commercial and government customers that were transferred to Agencourt for a period of two years from the date of the agreement.

The PathoGenome Database, a database consisting of proprietary and publicly available genetic information from over thirty microbial organisms, including organisms responsible for the most prevalent bacterial infections has, since 2001, been marketed, maintained and distributed by EraGen Biosciences. We retain our rights to use it and receive a percentage of subscription fees and royalties from subscriber discoveries, but we do not expect that this program will have a significant impact on our business moving forward.

Patents and Proprietary Technology

Our commercial success depends in part on our ability to obtain intellectual property protection on our methods, technologies and discoveries. To that end, our policy is to protect our proprietary technology primarily through patents.

We currently own or license approximately 50 issued U.S. patents, approximately 127 pending U.S. patent applications, 50 issued foreign patents and approximately 143 pending foreign patent applications. These patents and patent applications primarily relate to (1) the field of human and pathogen genetics, (2) the chemical composition, use, and method of manufacturing FACTIVE tablets, (3) metalloenzyme inhibitors, their uses, and their targets, and (4) DNA-Nanobinder compounds and their use as anti-infective therapeutics. Our material patents are as follows:

U.S. Patent No. 5,633,262 granted May 27, 1997, relating to quinoline carboxylic acid derivatives having 7-(4-amino-methyl-3-oxime) pyrrolidine substituent; licensed from LG Life Sciences; expiring June 15, 2015

U.S. Patent No. 5,776,944 granted July 7, 1998, relating to 7-(4-aminomethyl-3-methyloxyiminopyrroplidin-1-yl)-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1,8-naphthyridine-3-carboxylic acid; licensed from LG Life Sciences; expiring June 15, 2015

U.S. Patent No. 5,869,670 granted February 9, 1999, relating to 7-(4-aminomethyl-3-methyloxyiminopyrrolidin-1-yl)-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1,8-naphthyridine-3-carboxylic acid; licensed from LG Life Sciences; expiring June 15, 2015

U.S. Patent No. 5,962,468 granted October 5, 1999, relating to 7-(4-aminomethyl-3-methyloxyiminopyrrolidin-1-yl)-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1,8-naphthyridine-3-carboxylic acid; licensed from LG Life Sciences; expiring June 15, 2015

U.S. Patent No. 6,340,689 granted January 22, 2002, relating to methods of using quinolone compounds against atypical upper respiratory pathogenic bacteria; licensed from LG Life Sciences; expiring September 14, 2019

U.S. Patent No. 6,262,071 granted July 17, 2001, relating to methods of using antimicrobial compounds against pathogenic Mycoplasma bacteria; licensed from LG Life Sciences; expiring September 21, 2019

U.S. Patent No. 6,331,550 granted December 18, 2001, relating to methods of using of quinolone compounds against anaerobic pathogenic bacteria; licensed from LG Life Sciences; expiring September 21, 2019

U.S. Patent No. 6,455,540 granted September 24, 2002, relating to methods of Use of quinolone compounds against anaerobic pathogenic bacteria; licensed from LG Life Sciences; expiring September 21, 2019

U.S. Patent No. 6,423,690 granted July 23, 2002, relating to antibacterial agents; licensed from Vernalis; expiring February 5, 2019

U.S. Patent No. 6,441,042 granted August 27, 2002, relating to hydroxamic acid derivatives as antibacterials; licensed from Vernalis; expiring May 14, 2019

U.S. Patent No. 6,380,370 granted April 30, 2002, relating to *Staphylococcus epidermidis*; expiring August 13, 2018

U.S. Patent No. 6,551,795 granted April 22, 2003, relating to *Pseudomonas aeruginosa*; expiring February 18, 2019

U.S. Patent No. 6,562,958 granted May 13, 2003, relating to *Acinetobacter baumannii*; expiring June 4, 2019

U.S. Patent No. 6,583,275 granted June 24, 2003, relating to *Enterococcus faecium*; expiring June 30, 2018

U.S. Patent No. 6,583,266 granted June 24, 2003, relating to *Mycobacterium tuberculosis* and *leprae*; expiring June 24, 2020

U.S. Patent No. 6,605,709 granted August 12, 2003, relating to *Proteus mirabilis*; expiring April 5, 2020

U.S. Patent No. 6,6105,836 granted August 26, 2003, relating to *Klebsiella pneumoniae*; expiring January 27, 2020

U.S. Patent No. 6,617,156 granted September 9, 2003, relating to *Enterococcus faecalis*; expiring August 13, 2018

While it is difficult to assess the value of our intellectual property portfolio, the patents named above may provide a competitive advantage in certain instances in the pathogen and anti-infective field by requiring others to obtain a license from us if they wish to produce competing products.

Under our license agreement with LG Life Sciences, we obtained an exclusive license to develop and market gemifloxacin in certain territories. This license covers 11 issued U.S. patents and a broad portfolio of corresponding foreign patents and pending patent applications. These patents include claims that relate to the chemical composition of FACTIVE tablets, methods of manufacturing and their use for the prophylaxis and treatment of bacterial infections. The U.S. patents are currently set to expire at various dates, ranging from 2015, in the case of the principal patents relating to FACTIVE tablets, to 2019. We have filed patent term extension applications, covering the regulatory review process, for the principal patents. If granted, these extensions would extend the exclusivity period through 2017. We also have the exclusive right to use FACTIVE trademarks, trade names, domain names and logos in conjunction with the use or sale of the product in the territories covered by the license.

LG Life Sciences has the obligation under the agreement to diligently maintain its patents and the patents of third parties to which it has rights that, in each case, relate to gemifloxacin, the active ingredient in FACTIVE tablets. We have the right, at our expense, to control any litigation relating to suits brought by a third party alleging that the manufacture, use or sale of gemifloxacin in its licensed field in the territories covered by the license infringes upon our rights. We also have the primary right to pursue actions for infringement of any patent licensed from LG Life Sciences under the license agreement within the territories covered by the license. If we elect not to pursue any infringement action, LG Life Sciences has the right to pursue it. The costs of any infringement actions are first paid out of any damages recovered. If we are the plaintiff, the remainder of the damages are retained by us, subject to our royalty obligations to LG Life Sciences. If LG Life Sciences is the plaintiff, the remainder of the damages are divided evenly between us and LG Life Sciences, subject to our royalty obligations to LG Life Sciences.

LG Life Sciences, as owner of U.S. Patent Nos. 5,776,944 and 5,962,468, submitted requests for reexamination to the U.S. Patent & Trademark Office, or PTO, in order to place additional references into the record of each patent. Both requests were granted by the PTO. Patent 468 has been reexamined with relatively minor modifications to the claims and confirmed patentable over the submitted references. The reexamination of Patent 944 is currently pending. If the PTO does not confirm the claims in this patent as patentable, our patent protection with respect to FACTIVE tablets in the U.S. may be weakened.

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Under our agreement with Vicuron, we obtained an exclusive license to develop and market oral Ramoplanin in the United States and Canada. The patents that we license to Ramoplanin under our agreement with Vicuron include claims relating to methods of manufacturing Ramoplanin as well as methods increasing the yield of the active compound. We also have applications pending relating to various novel uses of Ramoplanin. The patent covering the chemical composition of Ramoplanin has expired. To provide additional protection for Ramoplanin, we rely on proprietary know-how relating to maximizing yields in the manufacture of Ramoplanin, and intend to rely on the five year data exclusivity provisions under the Hatch-Waxman Act.

Vicuron has the obligation under our agreement to prosecute patents relating to Ramoplanin that are made by Vicuron personnel or conceived jointly by our personnel and Vicuron s personnel. We have the obligation to prosecute patents relating to Ramoplanin that are made solely by our personnel. We have the right to control any suits brought by a third party alleging that the manufacture, use or sale of Ramoplanin in our licensed field in the United States or Canada infringes upon our rights. We will bear the costs of any such actions; provided that if we are obligated to pay any royalties or other payments to a third party to sell Ramoplanin as a result of this litigation, Vicuron is obligated to pay that expense. We also have the primary right to pursue actions for infringement of any patent licensed from Vicuron within the United States and Canada within our licensed field. Vicuron has the primary right to pursue actions for infringement of any patents that it licenses to us outside of our licensed field within the United States and Canada and for all purposes outside of the United States and Canada. If the party with the primary right to pursue the infringement action elects not to pursue it, the other party generally has the right to pursue it. The costs of any infringement actions are first paid out of any damages recovered and are then allocated to the parties depending upon their interest in the suit.

We have exclusively licensed rights from Vernalis for the research, development and commercialization of certain anti-infectives under Vernalis patent portfolio relating to metalloenzyme inhibitors (including peptide deformylase inhibitors), their uses and related targets.

Our own patent portfolio also comprises patents relating to DNA-nanobinder technology and their applications as anti-infective therapeutics. In addition, under our license with California Institute of Technology, we were granted rights to U.S. patents and patent applications related to DNA-nanobinder technology. Certain patents and patent applications relating to DNA-nanobinder technology resulted from research funded by the U.S. government.

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

FACTIVE tablets are approved for the treatment of community-acquired pneumonia of mild to moderate severity and acute bacterial exacerbations of chronic bronchitis. There are several classes of antibiotics that are primary competitors for the treatment of these indications, including:

- other fluoroquinolones such as Levaquin® (levofloxacin), a product of Ortho-McNeil Pharmaceutical, Inc., Tequin® (gatifloxacin), a product of Bristol-Myers Squibb Company, and Cipro® (ciprofloxacin) and Avelox® (moxifloxacin), both products of Bayer Corporation;

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- macrolides such as Biaxin® (clarithromycin), a product of Abbott Laboratories and Zithromax® (azithromycin), a product of Pfizer Inc.; and

- penicillins such as Augmentin® (amoxicillin/clavulanate potassium), a product of GlaxoSmithKline.

In addition, a new drug application for Ketek®, a ketolide antibiotic from Aventis Pharmaceuticals, has been submitted to the FDA and Ketek is currently marketed in Europe. Many generic antibiotics are also currently prescribed to treat these infections.

Ramoplanin is currently in development for the prevention of bloodstream infections caused by vancomycin-resistant enterococci (VRE). We have no knowledge of any product currently approved by the FDA for this indication, nor are we aware of any product candidate currently in clinical trials for this indication. It is possible that competition exists without our knowledge and that current discovery and preclinical efforts are ongoing for this indication. Ramoplanin is also in clinical development for the treatment of *Clostridium difficile*-associated diarrhea (CDAD). We are aware of two products currently utilized in the marketplace Vancomin® (vancomycin), a product of Eli Lilly, and metronidazole, a generic product for treatment of this indication. We are also aware of at least three companies with products in development for the treatment of CDAD a Geltex/Genzyme compound in Phase II; an ImmuCell compound in Phase I/II; and an Acambis compound in Phase I/II. It is also possible that other companies are developing competitive products for this indication.

We are also aware that Vicuron and Novartis Pharma are jointly developing PDF inhibitor agents that may compete with any PDF products we develop.

All of our other internal product programs are in early stages and are not yet indication specific. Our alliance-related product development programs are also all in preclinical stages, and it is therefore not possible to identify any product profiles or competitors for these product development programs at this time. Our industry is very competitive and it therefore is likely that if and when product candidates from our early stage internal programs or our alliance programs reach the clinical development stage or are commercialized for sale, these products will also face 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 substantially greater capital resources, facilities and human resources than we do.

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

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

- our ability and our partners ability to develop and commercialize therapeutic, vaccine and diagnostic products based upon our 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, clinical development and sales and marketing operations.

Because we rely primarily on in-licensing and acquisitions of products and product candidates to expand our portfolio, it is important to note that we may also face increasing competition for in-licensing and acquisition opportunities from leading pharmaceutical and biotechnology companies. We cannot be certain that we will be able to in-license product opportunities in the future or acquire new products. 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 product candidates that we develop or commercialize. The extent to which such regulation may apply to our collaborators or us will vary depending on the nature of the product. Virtually all of our or our collaborators pharmaceutical products will require regulatory approval by governmental agencies prior to commercialization. In particular, the FDA in the United States and similar health authorities in foreign countries subject human therapeutic and vaccine products to rigorous preclinical and clinical testing and other approval procedures. Various 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 lead product, FACTIVE tablets, has already received FDA marketing approval for the treatment of community-acquired pneumonia of mild severity and acute bacterial exacerbations of chronic bronchitis. Our most advanced product candidate, Ramoplanin, currently being studied for the prevention of bloodstream infections caused by vancomycin-resistant enterococci and treatment of *Clostridium difficile*-associated diarrhea, will be regulated by the Center for Drug Evaluation and Research (CDER). Products developed as a result of our development programs 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 and is appropriately manufactured.

Our collaborators or we may also 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, rather like that of obtaining a BLA or a NDA, 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 with safety and efficacy data and manufacturing information, and

attaining FDA approval for a specific intended use.

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. There are additional regulatory requirements for products marketed outside the United States governing the conduct of clinical trials, product licensing, advertising and promotion, post-approval reports, manufacturing, pricing and reimbursement.

As a post-marketing study commitment, the FDA has required a prospective, randomized study comparing FACTIVE tablets (5,000 patients) to an active comparator (2,500 patients) in patients with CAP or ABECB. This study will include patients of different ethnicities, to gain safety information in populations not substantially represented in the existing clinical trial program, specifically as it relates to rash. Patients will be evaluated for clinical and laboratory safety. This Phase IV trial is expected to commence proximate to the product launch in the U.S. The results of this trial could restrict our ability to commercialize FACTIVE tablets.

Manufacturing facilities that produce drugs, biologics or medical devices are also subject to extensive regulation both by the FDA and foreign regulatory authorities. These regulations require, among other things, that our facilities and the facilities of third parties, such as LG Life Sciences, that produce products for us, be registered with the FDA, comply with current Good Manufacturing Practices and pass periodic inspections by the FDA. Facilities in foreign countries may be subject to inspection by FDA, local regulators or both. Current Good Manufacturing Practices, or cGMP, require extensive recordkeeping, quality control, documentation and auditing to ensure that products meet applicable specifications. Failure to comply with these requirements can result in warning letters, requirements of remedial action, and, in the case of more serious failures, suspension of manufacturing, seizure or recall of product and fines and penalties. Compliance with these requirements can be time consuming, costly and can result in delays in product approval or product sales.

Sales and Marketing

We have rights to market FACTIVE tablets in North America and parts of Europe.

Our current plan is initially to market and sell FACTIVE tablets through our own sales and marketing organization in the U.S. We are currently planning to hire sales representatives that will focus on high-prescribing primary care physicians in large markets and on infectious diseases experts. We intend to seek a co-promotion partner in the U.S. for future periods to broaden our marketing efforts. We are also building a team of professionals with experience in medical education, insurance and government reimbursement, medical affairs, marketing, advertising and scientific communications throughout this year and into 2005. It is our plan to leverage the expertise of this sales and marketing team to penetrate the fluoroquinolone market with the launch of FACTIVE tablets in summer 2004 and introduce FACTIVE tablets to the medical community.

We believe that the commercial success of FACTIVE tablets, especially in territories outside of the U.S., will benefit from the additional resources that a pharmaceutical marketing partner would provide. We anticipate that we will rely upon a co-promotion partner in our licensed territories in Europe and Canada to facilitate the filing of required regulatory submissions, to assist with necessary reimbursement discussions and to help us market and sell the product in those territories.

We have the exclusive right to market Ramoplanin in the U.S. and Canada, if approved by Canadian regulatory authorities. We plan to use the sales and marketing team we build for FACTIVE tablets to facilitate commercialization of Ramoplanin in the U.S. and Canada.

Manufacturing

Under the terms of our licensing agreement with LG Life Sciences, LG Life Sciences has agreed to supply all of our anticipated commercial requirements for FACTIVE bulk drug substance and we have agreed to purchase all of our requirements for the bulk drug substance from LG Life Sciences. LG Life Sciences is expected to supply the FACTIVE bulk drug substance from its manufacturing facility in South Korea. In addition, LG Life Sciences is obligated to provide us with finished product until the termination or expiration of

LG Life Sciences agreement with SB Pharmco Puerto Rico, Inc., or SB Pharmco. LG Life Sciences has an agreement with SB Pharmco pursuant to which SB Pharmco will supply finished FACTIVE product to LG Life Sciences. The term of this agreement ends on June 30, 2004 but, subject to the satisfaction of certain requirements, may be extended by LG Life Sciences to September 30, 2004. We are currently in discussions with new providers of finished products to assume these responsibilities for subsequent periods. We estimate that it will take 12 to 18 months to qualify a new provider of finished products. We expect to obtain quantities of FACTIVE tablets from SB Pharmco that will provide us with sufficient inventory until the new provider can be qualified. If we are unable to qualify a new provider by the time that our supply of finished product to be received from SB Pharmco is exhausted, our supply of FACTIVE product would be interrupted.

The terms of our agreement for Ramoplanin obligate the licensor, Vicuron 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 cGMP.

Human Resources

As of December 31, 2003, we had 54 full-time equivalent employees, with 32 of these employees engaged in research and development activities and 22 of them conducting selling, marketing, general and administrative functions. Fourteen of our employees held Ph.D. or equivalent degrees and 15 more held other advanced degrees. Following the merger with Genesoft Pharmaceuticals in February 2004, we had 63 employees, of which 33 engage in research and development activities and 30 conduct selling, marketing, general and administrative functions. Currently, 18 of our employees hold Ph.D. or equivalent degrees and 17 more hold other advanced degrees.

None of our employees are 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 2003, we incurred aggregate rental costs, excluding maintenance and utilities, for our facility of approximately $1,079,000. We are sub-leasing the portions of our facility left vacant subsequent to our reduction in internally funded early-stage target discovery and the sale of our genomics services business to Agencourt. As of February 29, 2004, we had sub-leased approximately 16,000 square feet.

Subsequent to our merger with Genesoft, we also maintain West Coast operations at 7300 Shoreline Court, South San Francisco, California, where approximately 68,000 square feet of laboratory and administrative space is leased. The yearly base rent for the West Coast facility is approximately $3,938,000. The lease for this facility expires on March 31, 2011 and we have sub-leased to third parties approximately 30,200 square feet of the facility through December 31, 2004. We receive approximately $1,700,000 in yearly base rent from the West Coast sublease.

We are considering additional subleases and other options for portions of both our corporate headquarters and our West Coast facilities.

Item 3. ***Legal Proceedings***

None.

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

None.

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 sale prices for each fiscal quarter during 2002 and 2003 as reported by the National Association of Securities Dealers Quotation System.

	2002		2003	
	High	Low	High	Low
First Quarter	$ 7.200	$ 4.930	$ 2.030	$ 1.280
Second Quarter	5.810	2.000	3.700	1.465
Third Quarter	2.390	1.250	3.375	2.400
Fourth Quarter	2.480	1.000	3.460	2.640

As of February 20, 2004, there were approximately 1,081 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.

We maintain a website with the address www.genomecorp.com. We are not including the information contained on our website as a part of, or incorporating it by reference into, this Annual Report on Form 10-K. We make available free of charge through our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, and amendments to these reports, as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the Securities and Exchange Commission.

On September 29, 2003 and October 15, 2003, we completed a private placement to institutional investors of 5,220,000 shares of common stock at $2.50 per share resulting in proceeds of approximately $12 million, net of issuance costs. In connection with this private placement, we issued warrants to purchase 2,610,000 shares of common stock at an exercise price of $3.48 per share, subject to certain adjustments. These warrants remain exercisable for a period of five years and cannot be exercised during the six-month period immediately following the transaction. These securities were sold pursuant to the private placement exemption provided by Section 4(2) of the Securities Act of 1933, as amended. We relied on representations from the institutional investors to establish this exemption.

Item 6. ***Selected Consolidated Financial Data***

	For the Year Ended December 31,

	1999	2000	2001	2002	2003
Revenues:					
Biopharmaceutical	$ 18,162,056	$ 11,851,091	$ 18,438,286	$ 7,715,992	$ 7,009,175
Genomics services	6,665,529	13,594,143	17,302,239	15,270,863	2,049,438
Total revenues	24,827,585	25,445,234	35,740,525	22,986,855	9,058,613
Net loss	(3,940,075)	(5,846,839)	(10,090,302)	(34,017,025)	(29,788,752)
Net loss per common share	(0.21)	(0.27)	(0.45)	(1.48)	(1.13)
Weighted average common shares outstanding	18,627,045	21,376,685	22,572,427	22,920,875	26,289,876

	As of December 31,				
	1999	2000	2001	2002	2003
Cash and cash equivalents, restricted cash, warrant and long and short-term marketable securities	$ 26,778,026	$ 73,009,887	$ 67,341,249	$ 50,866,198	$ 28,665,032
Working capital	19,447,189	51,601,069	44,156,478	36,511,427	18,896,917
Total assets	45,443,236	90,251,004	82,739,598	65,845,134	40,516,315
Shareholders equity	28,846,957	72,687,452	66,731,938	35,416,724	29,940,104

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

Forward-Looking Statements

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 the future financial performance and other matters discussed in this document. The words may, will, should, plan, believe, estimate, intend, anticipate, project, and expect and similar expressions are intended to identify forwa 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 the successful commercialization of FACTIVE tablets, such as (i) our inability to successfully market the product due to competition from other competing drugs and (ii) our inability to recruit and retain a successful sales management team and sales force at market acceptance point.

- 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 of products based on our genomics information;

- our history of operating losses and our need to raise future capital to support our commercial activities, 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 committed to the clinical development and commercialization of new therapeutics to serve unmet medical needs. On February 6, 2004, we announced the completion of our merger with Genesoft Pharmaceuticals, a privately-held pharmaceutical company based in South San Francisco, California.

Our product portfolio is now led by the FDA-approved fluoroquinolone antibiotic FACTIVE (gemifloxacin mesylate) tablets, indicated for the treatment of community-acquired pneumonia of mild-to-moderate severity and acute bacterial exacerbations of chronic bronchitis. For the near term, we intend to focus our efforts on the launch of commercial sales of FACTIVE tablets for these indications. We anticipate the launch of FACTIVE will occur in the second half of 2004.

In addition, we are developing a novel antibiotic candidate, Ramoplanin, which is currently in clinical trials for the prevention and treatment of serious hospital-acquired infections. Ramoplanin is in a Phase III trial for the prevention of bloodstream infections caused by vancomycin-resistant enterococci and in a Phase II trial for the treatment of *Clostridium difficile*-associated diarrhea.

In the first quarter of 2003 and past fiscal years, we also received revenues from our genomics services business from selling, as a contract service business, high quality genomic sequencing information to our customers. As part of our continued evolution into a focused biopharmaceutical company, on March 14, 2003, we completed the sale of our genomics services business to privately held Agencourt Bioscience Corporation (Agencourt). As part of the agreement, we transferred our sequencing operations, including certain equipment and personnel to Agencourt. We received an up-front cash payment of $200,000 and shares of Agencourt s common stock. We will also receive a percentage of revenues from our former commercial and government customers, transferred to Agencourt, for a period of two years from the date of sale. We retain rights to our PathoGenome™ Database product, including all associated intellectual property, subscriptions and royalty rights on products developed by subscribers. Furthermore, we retained the capabilities necessary to satisfy our existing research needs. We do not expect the sale of the genomics services business to have a significant impact on our net loss during the next year because 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.

In connection with the sale of our genomics services business, we determined that certain equipment related to this segment would no longer be used and was abandoned subsequent to the sale. As a result, we revised the estimated useful lives of this equipment and recorded additional depreciation expense of $669,000 during the fourth quarter of 2002. We also evaluated and wrote down our excess inventory of disposables related to the genomics services business by $312,000 during the fourth quarter of 2002. Additionally, through this divestiture, we eliminated approximately 60 full-time positions, of which approximately 49 employees were not offered employment with Agencourt. We recorded a charge of approximately $691,000 in the first quarter of 2003, of which approximately $127,000 was related to the transfer of assets to Agencourt and approximately $564,000 was associated with the reduction in work force, such as severance costs and outplacement services. As of December 31, 2003, all payments related to both severance and outplacement services had been made.

In December 2003, the Company sold its pending applications related to the organism *Streptococcus pneumoniae* to Aventis Pasteur for a one-time cash payment of $3,000,000. The Company has recorded this payment as other income in its Consolidated Statements of Operations for the year ended December 31, 2003.

Previously, we received payments from our product discovery alliances based on license fees, contract research and milestone payments during the term of our alliances. 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 anticipate that we will also generate revenue from the sale of FACTIVE tablets following its launch in the second half of 2004.

The merger with Genesoft will be accounted for as a purchase by us under accounting principles generally accepted in the United States. Under the purchase method of accounting, we are considered the acquirer and the assets and liabilities of Genesoft will be recorded, as of the date of the merger of February 6, 2004, at their respective fair values and added to those of our Company. Reported financial condition and results of operations

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of our Company issued after February 6, 2004 will reflect Genesoft s balances and results after completion of the merger, but will not be restated retroactively to reflect the historical financial position or results of operations of Genesoft. Following February 6, 2004, the earnings of the combined company will reflect purchase accounting adjustments, including in-process research and development charges and amortization and depreciation expense for acquired tangible and intangible assets. The most significant of the intangible assets identified will have finite lives and relate to FACTIVE. These amounts will be amortized over their expected useful lives. Goodwill will also be recorded, however, pursuant to SFAS No. 141, Business Combinations and SFAS No. 142, Goodwill and Other Intangible Assets , goodwill will not be amortized but subject to annual impairment review.

We have incurred significant operating losses since our inception. As of December 31, 2003, we had an accumulated deficit of approximately $155.6 million. We expect to incur additional operating losses over the next several years due to the implementation of manufacturing, distribution, marketing and sales capabilities, as well as continued research and development efforts, preclinical testing and clinical trials

Major Research and Development Projects

FACTIVE (gemifloxacin mesylate) Tablets

In October 2002, Genesoft, now a subsidiary of ours, entered into a license and option agreement with LG Life Sciences to develop and commercialize gemifloxacin, a novel quinolone antibiotic, in North America, France, Germany, the United Kingdom, Luxembourg, Ireland, Italy, Spain, Portugal, Belgium, the Netherlands, Austria, Greece, Sweden, Denmark, Finland, Norway, Iceland, Switzerland, Andorra, Monaco, San Marino and Vatican City. The term of the agreement extends at least through gemifloxacin s patent life which currently expires in 2015 with respect to the principal patents for gemifloxacin, and the term could extend further depending upon several factors, including whether we obtain patent extensions and the timing of our commercial sale of the product in a particular country. The product was approved for sale in the United States in April 2003 for the treatment of acute bacterial exacerbation of chronic bronchitis and community-acquired pneumonia of mild to moderate severity.

Under the terms of our agreement, LG Life Sciences has agreed to supply and we are obligated to purchase from LG Life Sciences all of our anticipated commercial requirements for FACTIVE bulk drug substance. LG Life Sciences is expected to supply the FACTIVE bulk drug substance from its manufacturing facility in South Korea. LG Life Sciences has an agreement with SB Pharmco pursuant to which SB Pharmco will supply finished FACTIVE product to LG Life Sciences. The term of this agreement ends on June 30, 2004 but, subject to the satisfaction of certain requirements, may be extended by LG Life Sciences to September 30, 2004. We are currently in discussions with new providers of finished products to assume these responsibilities for subsequent periods. We estimate that it will take 12 to 18 months to qualify a new provider of finished products. We expect to obtain quantities of FACTIVE tablets from SB Pharmco that will provide us with sufficient inventory until the new provider can be qualified. We are also in the process of building a sales and marketing force in order to permit the launch of FACTIVE tablets in the second half of 2004. Since the launch of FACTIVE tablets is expected to take place in the second half of 2004, we do not expect sales of FACTIVE tablets to have a significant impact on the Company s revenues in 2004.

As a post-marketing study commitment, the FDA has required a prospective, randomized study comparing FACTIVE tablets (5,000 patients) to an active comparator (2,500 patients) in patients with CAP or ABECB. This study will include patients of different ethnicities, to gain safety information in populations not substantially represented in the existing clinical trial program, specifically as it relates to rash. Patients will be evaluated for clinical and laboratory safety. This Phase IV trial is expected to commence proximate to the product launch in the U.S.

Our ability to successfully launch FACTIVE tablets in the second half of 2004 is subject to a number of risks, including the results of the Phase IV trial described above, our ability to successfully hire the sales and marketing staff needed for the launch, the ability of our manufacturing partners to timely produce the needed quantities of the drug in compliance with regulations and competition in the marketplace from competing

anti-infective products. If we are unable to successfully launch FACTIVE tablets in the second half of 2004, our operations, financial position and liquidity would be negatively affected to a significant, and possibly material, degree.

We are also seeking to expand the commercial opportunities for FACTIVE through additional development and clinical study plans for the product. As part of the FACTIVE development program, several studies in the acute bacterial sinusitis, or ABS, arena were completed. We are in the process of discussing with the FDA activities related to the filing of an NDA. We anticipate filing an NDA for this indication in 2005. Our ability to achieve this goal, however, is subject to a number of risks, including safety risks related to the drug, such as rash, our ability to hire qualified clinical development and regulatory personnel and the possibility that the FDA may find that our clinical data fails to establish that the drug is effective or safe to treat this indication. As a result of these many risks and uncertainties, we can not predict when material cash inflows from our ABS program will commence, if ever. If we fail to meet our goal of filing the NDA by 2005, our market for FACTIVE will be restricted and this would have a negative impact on our operations, financial position and liquidity.

In addition, we are developing an intravenous formulation of gemifloxacin. We expect that this intravenous formulation will undergo a Phase I bioequivalence study in the coming months. Pending a successful outcome of the first study, we plan to conduct a single Phase III trial of the intravenous formulation before pursuing market approval from the FDA.

Ramoplanin

Our ongoing clinical trials and other development activities for Ramoplanin have constituted our most significant research and development project comprising 23% of total research and development expenditures for fiscal 2001 (development activity and associated expense did not commence until the fourth quarter of 2001 upon our acquisition of an exclusive license for the product), 43% of total research and development expenditures for fiscal 2002 and 49% of total research and development expenditures for fiscal 2003. Expenses for Ramoplanin comprise 46% of the total research and development expense since inception of the project.

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 development of Ramoplanin in the United States. The product candidate is 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 the bulk product purchases and royalties is expected to be approximately 26% of our net product sales.

As of December 31, 2003, the status of the Ramoplanin clinical program was as follows:

- In a Phase III clinical trial for the prevention of bloodstream infections caused by vancomycin-resistant enterococci (VRE).
- In a Phase II clinical trial to assess safety and efficacy of Ramoplanin to treat *Clostridium difficile*-associated diarrhea (CDAD).
- In a pilot study to examine Ramoplanin s potential role in controlling the spread of nosocomial bacteria.

Other supportive clinical trials, Chemistry Manufacturing Controls (CMC), and development activity, such as formulation, scale-up and validation, required for registration are ongoing or being planned.

The initial goal of the Ramoplanin program is to obtain marketing approval from the FDA for the VRE and CDAD indications. We are also likely to explore programs for other indications to be determined. The successful commercialization of Ramoplanin is subject to many risks and uncertainties, including delays in the progress of our clinical trials, and increased cost, due to the pace of enrollment of patients in the trials, our inability to obtain product approval due to negative, inconclusive or insufficient clinical data and our inability to successfully

market our product due to competition from other competing drugs. As a result of these many risks and uncertainties, we can not predict when material cash inflows from our Ramoplanin project will commence, if ever. A failure to obtain a marketing approval for Ramoplanin and to successfully commercialize the drug would have a significant negative impact on our operations, financial position and liquidity.

Biopharmaceutical Alliances

Another major research and development focus of ours has been the support we have provided to fulfill our research obligations with our pharmaceutical company partners under our strategic alliances.

The research and development expense to support these alliances was 30% of total research and development expenses in fiscal 2001, 16% of total research and development expenses in fiscal 2002 and 23% of total research and development expenses in fiscal 2003. Research and development expense to support our alliances was 35% of the total research and development expense from January 1, 1995 through December 31, 2003. Our first alliance was formed in 1995.

A summary of the specific biopharmaceutical alliances that have composed our research and development program, including date initiated, alliance goal and status of each alliance, follows:

Biopharmaceutical Alliances	Goal	Status
AstraZeneca, August 1995	Develop pharmaceutical, vaccine and diagnostic products effective against gastrointestinal infections or any other disease caused by Helicobacter pylori (H. pylori).	The contract research phase of the alliance concluded in August 1999 and the program transitioned into AstraZeneca s pipeline. The program is currently in the lead optimization phase.
Schering-Plough, December 1995	Identify new gene targets for the development of novel antibiotics utilizing our Staphylococcus aureus (S. aureus) genomic database.	We completed our research obligations in March 2002 and validated drug targets and assays were turned over to Schering-Plough. Schering-Plough has advanced the program into high-throughput screening for drug candidates.
Schering-Plough, December 1996	Develop new pharmaceuticals for the treatment of asthma through the identification of genes and associated proteins.	In December 2002, we completed our research obligations and Schering-Plough has advanced the program into high-throughput screening for drug candidates.
Schering-Plough, September 1997	Develop new pharmaceutical products to treat fungal infections.	We completed our research obligations in March 2002 and validated drug targets and assays were turned over to Schering-Plough. Schering-Plough has advanced the program into high-throughput screening for drug candidates.
bioMérieux, September 1999	Develop, manufacture and sell *in vitro* pathogen diagnostics products for human clinical and industrial applications.	In November 2003, we completed our contract research obligations under the terms of this agreement.

Biopharmaceutical Alliances	Goal	Status
Wyeth, December 1999	Develop drugs based on our genetic research to treat osteoporosis.	In December 2003, we completed our research obligations and Wyeth has advanced the program into high-throughput screening for drug candidates.
Amgen, December 2002	Identify and develop novel therapeutic agents for bone diseases, including osteoporosis based on our genetic research	Both companies have agreed to conclude the research collaboration effective April 7, 2004. With the conclusion of this research program, the Company will retain certain intellectual property and licensing rights related to its gene discovery under this alliance.

Our ability to obtain the goal for each of these alliances is subject to numerous risks, including our inability to realize the potential of our initial discoveries due to scientific failures or lack of skilled personnel. In addition, we are heavily dependant upon our alliance partners to carry out product discovery, clinical development and commercialization activities. Our success in achieving our goals and obtaining further milestone payments depends, for example, upon whether our alliance partner identifies any compounds, through high-throughput screening and lead optimization that warrant clinical development, whether any such compounds demonstrate the required safety and efficacy in clinical trials in order to support a regulatory approval and whether they are able to successfully manufacture and commercialize the product. Due to these uncertainties, we can not be certain if we will obtain additional milestone payments under our alliances or predict when material cash inflows from products generated by these alliances will commence, if ever.

Internally Funded Research Program

As part of our strategic decision to concentrate on development and commercialization of our own products, we adopted a plan in 2003 to substantially reduce our research effort in internally funded early-stage target discovery programs. Under this plan, we eliminated 33 full-time positions and recorded a restructuring charge of approximately $5.3 million in 2003. This charge consisted of a reduction in work force, such as severance costs, outplacement services and a non-cash charge for the acceleration of vesting of previously granted stock options, as well as impairment charges related to the value of laboratory and computer equipment no longer used in operations.

Prior to our strategic shift away from early stage drug discovery, we conducted our own internally funded research programs, falling into two primary categories:

- The discovery and research of potential drug candidates, primarily in the anti-infective area. Depending on the potential indication, we sought partners to support further development of our discoveries. To date, our internal efforts have produced two novel lead series, which have reached the optimization stage.

- The acquisition of assets, primarily population resources, combined with our disease gene identification platform with the goal of making discoveries that would facilitate new biopharmaceutical alliances.

As a combined category, these research efforts represented 47% of total research and development expenditures in fiscal 2001, 41% of expenditures in fiscal 2002 and 28% of expenditures in fiscal 2003. These efforts comprised 48% of the total research and development expense during January 1, 1995 through December 31, 2003.

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Our current portfolio of internal drug discovery programs focuses on bacterial infections and the growing need to develop antibacterial compounds with novel mechanisms of action. Our research program is now focused on the optimization of second-generation, orally-available PDF inhibitors with the potential to target the broader community-based antibiotic market. Several compounds have been identified with improved properties, including good activity against *H. influenzae.* With continued success, we anticipate selecting a development candidate and initiating IND-enabling studies. Additionally, as a result of our internal drug discovery efforts, we have identified two novel chemical series ready to enter the lead optimization phase with a partner. These two lead series are aimed at novel, broad-spectrum targets and have the potential to be new classes of antibacterials. In addition to these lead compounds, we have identified hit series on six additional antimicrobial screens.

Our ability to achieve our goals for our internally funded research program is subject to numerous risks, including our inability to make new discoveries due to scientific failures or lack of skilled personnel. Even if we succeed in identifying novel lead series or making genetic discoveries related to a disease, we may not be successful in developing these discoveries further due to lack of internal resources and the inability to find a strategic partner in an increasingly competitive environment for strategic alliances. Due to all of these uncertainties, we can provide no assurance that we will ever receive any material cash inflows from this program.

Critical Accounting Policies & Estimates

We have identified the policies below as critical to our business operations and the understanding of our results of operations. The impact and any associated risks related to these policies on our business operations is discussed throughout Management s Discussion and Analysis of Financial Condition and Results of Operations where such policies affect our reported and expected financial results. For a detailed discussion on the application of these 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 Report requires us to make estimates and assumptions that affect the reported amount of assets and liabilities, disclosure of contingent assets and liabilities at the date of our consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Revenue Recognition

Biopharmaceutical revenues consist of license fees and contract research and milestone payments from alliances with pharmaceutical companies. Genomics services revenues consist of government grants, fees and royalties received from custom gene sequencing and analysis services and subscription fees from the PathoGenome™ Database.

Revenues from contract research, government grants, 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. The percentage of services performed related to contract research, government grants and custom gene sequencing and analysis services is based on the ratio of the number of direct labor hours performed to date to total direct labor hours the Company is obligated to perform under the related contract, as determined on a full-time equivalent basis. Revenues from PathoGenome™ Database subscription fees are recognized ratably over the term of the subscription agreement.

Amounts received for license fees are deferred and recognized ratably over the performance period in accordance with Staff Accounting Bulletin (SAB) No. 104, Revenue Recognition. Milestone payments will be recognized upon achievement of the milestone as long as the milestone is non-refundable, 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.

Clinical Trial Expense Accrual

Our clinical development trials related to Ramoplanin are primarily performed by outside parties. It is not unusual at the end of each accounting period for us to estimate both the total cost and time period of the trials and the percent completed as of that accounting date. We also adjust these estimates when final invoices are received. During 2003, we adjusted our accrual for clinical trial expenditures to reflect our most current estimate of liabilities outstanding to outside parties, resulting in a favorable change in estimate in the accrual for clinical development expenditures. We believe that the estimates that we made as of December 31, 2003 are reflective of the actual expenses incurred as of that date. However, readers should be cautioned that the possibility exists that the timing or cost of the Ramoplanin clinical trials might be longer or shorter and cost more or less than we have estimated and that the associated financial adjustments would be reflected in future periods.

Results of Operations

Years Ended December 31, 2002 and 2003

Revenues

Total revenues decreased 61% from $22,987,000 in 2002 to $9,059,000 in 2003. Biopharmaceutical revenues decreased 9% from $7,716,000 in 2002 to $7,009,000 in 2003, which reflects primarily lower contract research revenue as a result of the completion last year of our research obligations with Schering-Plough, partially offset by sponsored research revenue and a milestone payment earned from our alliance with Amgen, which we entered into in December 2002.

Revenues from genomics services decreased 87% from $15,271,000 in 2002 to $2,049,000 in 2003 primarily due to the sale of our genomics services business to Agencourt in March 2003, as well as the expiration of our government grants with the National Human Genome Research Institute to participate in the Human Genome and Mouse (Rat) Genome sequencing projects. Revenue from the genomics services business will terminate in 2005 upon the expiration of our agreement with Agencourt.

There will be a shift in the revenue mix in 2004. We expect our revenues derived from both our biopharmaceutical alliances and genomic services to continue to decrease in comparison to prior years and an increase in commercial product revenues as we launch the sale of our FACTIVE tablets in the second half of 2004.

Costs and Expenses

Total costs and expenses decreased 26% from $56,888,000 in 2002 to $42,267,000 in 2003. Cost of services decreased 87% from $15,041,000 in 2002 to $1,903,000 in 2003 due to the sale of the genomics services business to Agencourt in March 2003.

Research and development expenses include internal research and development expenses, research funded pursuant to arrangements with our strategic alliance partners, as well as clinical development costs and expenses. Research and development expenses primarily consist of salaries

and related expenses for personnel and the cost of materials used in sequencing activities and research and development. Other research and development expenses include fees paid to consultants and outside service providers, information technology and facilities costs. Research and development expenses decreased 32% from $32,466,000 in 2002 to $22,163,000 in 2003. This decrease was primarily due to (i) the reduction in our effort in internally funded early-stage drug discovery research programs totaling $6,974,000 under our restructuring plan, which was implemented in May 2003, (ii) the decrease in cost and expenses associated with the decrease in biopharmaceutical revenue of approximately $232,000 and (iii) the reduction in expenses incurred in the clinical development of Ramoplanin of approximately $3,097,000. The reduction in clinical development expenses is primarily due to a decrease in expenditures to outside parties of $5,144,000, partially offset by higher support expenditures such as personnel, consulting and material costs of $2,047,000.

As part of our effort to reduce costs and expenses, we have substantially reduced our research effort in internally funded early-stage target discovery programs. In connection with the scale back of our activities, we recorded a restructuring charge of approximately $5,257,000. Approximately $1,507,000 was related to a reduction in work force and included severance costs, outplacement services and a non-cash charge for the acceleration of vesting of previously granted stock options for employees affected by the initiative. The restructuring charge also included approximately $3,750,000 of impairment charges related to the value of laboratory and computer equipment no longer used in operations.

During 2003, we also recorded a one-time charge to convertible debt retirement expense of $5,540,000 for the early conversion of convertible notes payable issued to two institutional investors in March 2002, which consisted of $3,862,000 for the fair value of the incremental shares issued under the Amendment, Redemption and Exchange Agreement dated June 4, 2003 with the investors, $150,000 for the incremental fair value of the exchange warrants using the Black-Scholes option pricing model, as well as $574,000 of unamortized closing costs related to the original agreement with the investors and $954,000 of unamortized cost related to the value of the original warrants issued to the investors.

Selling, general and administrative expenses decreased 21% from $9,382,000 in 2002 to $7,404,000 in 2003 driven principally by the restructuring plan, which resulted in a reduction in support staff and personnel related expenditures, consulting fees and hiring expenses.

Our spending patterns will continue to evolve. We expect the expenses in early-stage research to continue to decrease over the year, as we reduce our focus in this arena. However, in order to realize the commercial launch of FACTIVE tablets in the second half of 2004, we will experience a significant increase in hiring as we build a sales and marketing organization, expand the medical/development organization to support additional FACTIVE development and commercialization, continue support for the development of Ramoplanin and build the infrastructure necessary to support these expansions.

Other Income and Expense

Interest income decreased 67% from $1,769,000 in 2002 to $581,000 in 2003 reflecting lower interest rate yields from investments, as well as a decrease in funds available for investment.

Interest expense decreased 49% from $1,936,000 in 2002 to $990,000 in 2003 reflecting lower interest expense incurred this year due to the early retirement of the convertible notes payable, as well as the pay-off of an equipment financing arrangement in the first quarter of 2003.

In 2002, we recorded a gain on the sale of fixed assets of $52,000. In 2003, we recorded a gain on the sale of fixed assets of approximately $183,000, generated from the sale of certain scientific and computer equipment of approximately $310,000, partially offset by a loss on the transfer of fixed assets associated with sale of the genomics services business to Agencourt of approximately $127,000.

Other Income includes a payment from Aventis Pasteur for the transfer to Aventis of our patent portfolio relating to *Streptococcus pneumoniae (S. pneumoniae),* as well as a realized gain related to the sale of Vicuron common stock.

We expect an increase in interest expense in 2004 due to the issuance of $22 million of convertible promissory notes to note holders of Genesoft in connection with the merger. The accrued interest is not due until the earlier of (i) the conversion of the promissory notes into shares of our common stock or (ii) the maturity date of five years from the closing date of the merger.

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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.

Revenue from genomics 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 Database business as a result of third parties not renewing their database subscriptions.

Costs and Expenses

Total costs and expenses increased 16% from $48,949,000 in 2001 to $56,888,000 in 2002. Cost of services decreased 7% from $16,140,000 in 2001 to $15,041,000 in 2002 primarily due to decreased costs and expenses associated with the above mentioned decrease in genomics 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 $24,041,000 in 2001 to $32,466,000 in 2002. This planned increase was primarily due to an increase in expenses incurred in the clinical development of Ramoplanin of approximately $8,340,000, as well as increased investment in our internal drug discovery programs, specifically in the area of anti-infective and chronic human diseases, of $2,135,000. These increases in research and development expenses were partially offset by a decline in research funded under our product discovery alliances of approximately $2,060,000.

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

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 $804,000 related to the amortization of deferred issuance costs and warrants issued in connection with the convertible notes payable.

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. Beginning in 2004, we also anticipate generating cash from the sale of FACTIVE tablets following its launch in the second half of this year.

As of December 31, 2003, we had cash, cash equivalents and short-term marketable securities of approximately $28,665,000.

On February 6, 2004, subsequent to year-end, in conjunction with the merger with Genesoft, we sold 16.8 million shares of our common stock at $5.25 per share resulting in proceeds received of approximately $81 million, net of issuance costs. In October 2003, we completed a private placement of 5,220,000 shares of common stock at $2.50 per share resulting in proceeds of approximately $12.1 million, net of issuance costs. In connection with this private placement, the Company issued warrants to purchase 2,610,000 shares of common stock at an exercise price of $3.48 per share, subject to certain adjustments. These warrants remain exercisable for a period of five years. Additionally, we sold 146,333 shares of common stock to Amgen in 2003, a strategic alliance partner, resulting in gross proceeds of approximately $500,000.

In March 5, 2002, we sold convertible notes payable to two institutional investors in a private placement transaction, raising $15 million in gross proceeds. 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. 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.

In June 2003, we entered into an Amendment, Redemption and Exchange Agreement with the two institutional investors providing for (i) the redemption in cash of a portion of the 6% Convertible Notes due December 31, 2004, (ii) the conversion of the remaining portion of the convertible notes into our common stock and (iii) the issuance to the investors of new warrants in exchange for warrants previously held by the investors.

Under the terms of the agreement, we redeemed an aggregate of $10,000,000 in principal amount of the convertible notes for a cash payment of $10,000,000 to the investors, and the related accrued and unpaid interest on such principal amount of the convertible notes for a cash payment of an aggregate of $254,795 to the investors. The conversion price of the remaining $5,000,000 in principal amount of the convertible notes was amended to equal $2.5686 per share and the investors converted the remaining amount of the convertible notes, plus related accrued and unpaid interest, into 1,996,184 shares of our common stock. We also issued new warrants in exchange for the warrants that were previously issued to the investors. The new warrants have a term of five years from the issuance date, are immediately exercisable and allow the investors to purchase in the aggregate up to 535,806 shares of our common stock at an exercise price of $3.37 per share. The new warrants include provisions for adjustment of the exercise price and the number of shares issuable upon exercise in the event of stock splits, stock dividends, reverse stock splits, and issuances by us of shares of our capital stock at prices below the exercise price or the fair market value of the common stock if higher than such exercise price. We had also granted the investors a right of participation to purchase up to 33.33% of the amount of securities sold to investors in non-registered or shelf capital raising transactions (subject to certain exceptions), provided that if any such transaction exceeds $15,000,000, then for the portion of the transaction that exceeds $15,000,000, the investors have the right to purchase up to 20% of such excess amount sold to investors. In addition, each investor shall have the right to purchase at least $1,000,000 of securities in any such transaction. The rights described in this paragraph are effective until the second anniversary of the closing date of the transaction.

We received payments of approximately $19,500,000, $6,454,000 and $6,765,000 in 2001, 2002 and 2003, respectively, from our product discovery partners consisting of up-front license fees, contract research funding, subscription fee, milestone payments and expense reimbursement.

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We have various arrangements under which we have financed certain office and laboratory equipment and leasehold improvements. We had an aggregate of approximately $1,458,000 outstanding under our borrowing arrangements at December 31, 2003. This amount is repayable over the next 13 months, with $1,167,000 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, 2003.

Our operating activities used cash of approximately $16,603,000 in 2003 primarily due to our net loss for operations and decreases in accounts payable, clinical trial expense accrual and deferred revenues. These uses of cash were partially offset by decreases in accounts receivable, unbilled costs and fees, prepaid expenses, as well as non-cash charges, such as depreciation and amortization, restructuring charge, convertible debt retirement expense, and interest expense. Our operating activities used cash of approximately $26,140,000 in 2002 primarily due to our net loss from operations and an increase in accounts receivables, unbilled costs and fees as well as a decrease in 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 primarily due to a net loss from operations and an increase in prepaid expenses and other assets, as well as a decrease in deferred revenue. These uses of cash were partially offset by a decrease in interest receivable, accounts receivable and unbilled costs and fees, as well as an increase in accounts payables and accrued liabilities.

Our investing activities provided cash of approximately $16,116,000, $126,000 and $25,302,000 in 2001, 2002 and 2003, respectively, primarily through the conversion of marketable securities to cash and cash equivalents and proceeds received from sale of property and equipment. These sources of cash were partially offset by purchases of marketable securities, equipment and additions to leasehold improvements, as well as increases in other assets in 2002 and 2003. Additionally, the Company issued a $6.2 million bridge loan to Genesoft in 2003 in connection with the merger of the two companies.

Capital expenditures, consisting of purchases of laboratory, computer, and office equipment, totaled $121,000 during 2003, which was significantly lower than previous years as we shifted our focus away from early-stage drug development programs.

Our financing activities provided cash of approximately $1,142,000 in 2003 primarily from the private placement of common stock of approximately $12,650,000, net of issuance costs, proceeds received from issuances of stock from exercise of stock options and under employee stock purchase plan of approximately $952,000, as well as proceeds received from a legal claim with an investor of approximately $585,000. These proceeds from financing activities were partially offset by cash payment of $10 million in the redemption of the convertible notes, as well as cash payments of long-term obligations of approximately $3,045,000. Our financing activities provided cash of approximately $14,337,000 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 of approximately $453,000. These proceeds from financing activities were partially offset by payments of long-term obligations of $4,629,000. Our financing activities provided cash of approximately $545,000 in 2001 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, 2003, we had net operating loss carryforwards of approximately $144,170,000 and $120,939,000 available to reduce federal and state taxable income, if any. In addition, we also had tax credit carryforwards of approximately $12,240,000 to reduce federal and state income tax, 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%. Additionally, certain of our losses have begun to expire due to time, not limitations.

We believe that, under our current rate of investment in development programs, as well as our effort to launch FACTIVE, that our existing capital resources, including the $81 million received from the sale of common stock in connection with our offering related to the merger with Genesoft, are adequate for at least eighteen months of operations. There is no assurance, however, that changes in our plans or events affecting our operations will not result in accelerated or unexpected expenditures.

We expect to experience a significant increase in hiring as we build a sales and marketing organization in order to launch FACTIVE tablets, expand the medical/development organization to support additional FACTIVE development and commercialization, continue support for the development of Ramoplanin and build the infrastructure necessary to support these expansions. We would expect this growth, particularly in the sales and marketing areas, to continue during 2005.

Contractual Obligations

Our major outstanding contractual obligations relate to our convertible promissory notes and our facility leases. The following table summarizes our significant contractual obligations and the effect such obligations are expected to have on our liquidity and cash flow in future periods (in thousands):

	2004	2005	2006	2007	2008	2009 & Thereafter
Operating Leases	$ 5,030	$ 5,170	$ 5,277	$ 4,366	$ 4,519	$ 8,865
Sublease Income	(2,070)	(356)	(312)			
	$ 2,960	$ 4,814	$ 4,965	$ 4,366	$ 4,519	$ 8,865
Capital lease payable (a)	1,812	292				
Convertible promissory notes (b)						28,474
Total contractual obligations	$ 4,772	$ 5,106	$ 4,965	$ 4,366	$ 4,519	$ 37,339

(a) Includes interest payments.

(b) Upon the closing of the merger, we exchanged approximately $22 million of Company convertible promissory notes for a like principal amount of Genesoft promissory notes. The convertible promissory notes bear an interest rate of 5% per annum and have a maturity date of five years from the closing date. The convertible promissory notes are convertible into shares of our common stock at the holder s election at any time at a price per share equal to $6.6418, subject to subsequent adjustment. In addition, following the one year anniversary of the closing of the merger, we will have the right to force conversion if the price of our common stock closes above 150% of the then effective conversion price for 15 consecutive trading days. The convertible promissory notes payable of $28.5 million at maturity date includes $6.2 million of accrued interest payable

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 $112,000 decrease in the fair value of our investments as of December 31, 2003. 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, 2003, we had $1.5 million outstanding under our $3,500,000 line of credit that bears interest at the prevailing LIBOR rate (1.21% at December 31, 2003) plus 1.50%. A 10% increase in market rates would have increased our interest expense by approximately $2,000 in fiscal 2003.

As of December 31, 2003, 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.

In connection with the closing of the merger of Genesoft, we assumed approximately $22 million in Genesoft debt, restructured at a 5% annual interest rate, by issuing promissory notes of the Company that are convertible, at the option of the holder, into shares of the Company s common stock at a price of $6.6418 per share. The interest rates on our convertible notes payable 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.

Item 9A. ***Controls and Procedure***

We currently have in place systems relating to disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934). Our principal executive officer and principal financial officer evaluated the effectiveness of these disclosure controls and procedures as of the end of our fiscal year ended December 31, 2003 in connection with the preparation of this annual report. They concluded that the controls and procedures were effective and adequate at that time. There were no significant changes in the Company s internal control over financial reporting during the fourth quarter of fiscal 2003 that have materially affected, or are reasonably likely to materially affect the Company s control over financial reporting.

PART III

Pursuant to General Instruction G(3) to Form 10-K, the information required for Part III, Items 10 (other than Code of Ethics, which is set forth below), 11, 12, 13 and 14, is incorporated herein by reference from the Company s proxy statement for the Annual Meeting of Shareholders to be held on April 13, 2004.

Item 10. ***Code of Ethics***

We have adopted a code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer and controller. That code is part of the Company s code of ethics and conduct which is available free of charge on our website (www.genomecorp.com). We intend to include on our website any amendment to, or waiver from, a provision of our code of ethics that applies to the Company s principal executive officer, principal financial officer, principal accounting officer and controller that relates to any element of the code of ethics definition enumerated in Item 406(b) of Regulation S-K.

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.

(3) List of Exhibits

Exhibit No.	Description
2.1	Agreement and Plan of Merger and Reorganization(36)
3.1	Restated Articles of Organization and By-laws(1)
3.2	Amendment dated January 5, 1982 to Restated Articles of Organization(2)
3.3	Amendment dated January 24, 1983 to Restated Articles of Organization(3)
3.4	Amendment dated January 17, 1984 to Restated Articles of Organization(4)
3.5	Amendment dated October 20, 1987 to the By-laws(7)
3.6	Amendment dated December 9, 1987 to Restated Articles of Organization(8)
3.7	Amendment dated October 16, 1989 to the By-law(9)
3.8	Amendment dated January 24, 1994 to Articles Restated Articles of Organization(12)
3.9	Amendment dated August 31, 1994 to Restated Articles of Organization(12)
3.10	Amendment dated March 15, 2001 to Restated Articles of Organization(25)
3.11	By-Laws of Genome Therapeutics Corp (as amended through July 24, 2001)(26)
4.1	Form of Note dated March 5, 2002 received by Smithfield Fiduciary LLC and the Tail Wind Fund, Ltd.(27)
4.2	Amendment, Redemption and Exchange Agreement between the Company and Smithfield Fiduciary LLC, dated June 4, 2003(32)
4.3	Amendment, Redemption and Exchange Agreement between the Company and The Tail Wind Fund, dated June 4, 2003(32)
4.4	Form of Purchase Warrant issued to Smithfield Fiduciary LLC and the Tail Wind Fund Ltd.(32)
4.5	Employee Stock Purchase Plan(33)
4.6	Form of Warrant issued in private placement(34)
10.1	Incentive Stock Option Plan and Form of Stock Option Certificate(1)
10.2	Genome Therapeutics Corp. (f/k/a Collaborative Research) Incentive Savings Plan(5)
10.3	Amendment dated November 4, 1986 to the Genome Therapeutics Corp. (f/k/a Collaborative Research) Incentive Savings Plan dated March 1, 1985(6)
10.4	1991 Stock Option Plan and Form of Stock Option Certificate(10)
10.5	Lease dated November 17, 1992 relating to certain property in Waltham, Massachusetts(11)

10.6 Lease dated June 3, 1993 relating to certain property in Waltham, Massachusetts(11)

Exhibit No.	Description
10.7	Lease Amendment dated August 1, 1994 relating to certain property in Waltham, MA(12)
10.8	1993 Stock Option Plan and Form of Stock Option Certificate(12)
10.9	Agreement between the Company and AstraZeneca PLC (f/k/a Astra Hassle AB) dated August 31, 1995(13)*
10.10	Form of director Stock Option Agreement and schedule of director options granted(14)
10.11	Collaboration and License Agreement between the Company, Schering Corporation and Schering-Plough Ltd., dated as of December 6, 1995(15)*
10.12	Lease amendment dated November 15, 1996 to certain property in Waltham, MA(16)
10.13	Collaboration and License Agreement between the Company, Schering Corporation and Schering-Plough Ltd., dated as of December 20, 1996(17)*
10.14	Collaboration and License Agreement between the Company and Schering Corporation, dated September 22, 1997(18)*
10.15	Collaboration and License Agreement between the Company and Schering-Plough Ltd. dated September 22, 1997(18)*
10.16	1997 Directors Deferred Stock Plan(19)
10.17	1997 Stock Option Plan(19)
10.18	Collaboration and License Agreement between the Company and American Home Products, Inc., acting through its Wyeth-Ayerst Division, dated December 20, 1999(21)
10.19	Collaboration and License Agreement between Genome Therapeutics Corporation and bioMerieux Incorporated dated as of September 30, 1999(22)
10.20	Registration Rights Agreement between the Company and bioMerieux Alliance as dated September 30, 1999(23)
10.21	2001 Incentive Plan(24)
10.22	Stock Option Agreements with Steven M. Rauscher(24)
10.23	Employment Letter with Steven M. Rauscher(26)
10.24	Purchase Agreement dated March 5, 2002 among Smithfield Fiduciary LLC, The Tail Wind Fund, Ltd. and the Company(27)
10.25	Registration Rights Agreement dated March 5, 2002 among Smithfield Fiduciary LLC, The Tail Wind Fund, Ltd. and the Company(27)
10.26	License and Supply Agreement between the Company and Biosearch Italia, S.P.A., dated October 8, 2001(29)*
10.27	Research Collaboration and License Agreement between the Company and Amgen Inc., dated December 20, 2002(30)*
10.28	Stock Purchase Agreement between the Company and Amgen Inc., dated December 20, 2002(30)*
10.29	Letter Agreement between the Company and Biosearch Italia, S.P.A., dated October 22, 2002 (30)*
10.30	Retirement Letter with Robert J. Hennessey(31)
10.31	Employment Letter with Stephen Cohen(31)

Exhibit No.	Description
10.32	Employment Letter Richard Labaudiniere PhD(31)
10.33	Employment Letter with Martin D. Williams(31)
10.34	Form of Subscription Agreement for Private Placement(34)
10.35	Registration Rights Agreement for Private Placement(34)
10.36	Separation Agreement with Richard Labaudiniere, dated July 9, 2003(35)
10.37	Note Amendment and Exchange Agreement dated as of November 17, 2003, by and between Genome Therapeutics Corp. and certain creditors of GeneSoft Pharmaceuticals, Inc.(37)
10.38	Registration Rights Agreement dated as of November 17, 2003, by and between Genome Therapeutics Corp. and certain creditors of GeneSoft Pharmaceuticals, Inc.(37)
23.1	Consent of Ernst & Young LLP Independent Public Accountants(38)
31.1	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act(38)
31.2	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act(38)
32.1	Certification of the Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act(38)
32.2	Certification of the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act(38)
99.1	Risk Factors(38)

* 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.

(5) 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.

(6) 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.

(7) 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.

(8) 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.

(9) 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.

(10) 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.

(11) 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.

(12) 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.

(13) 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.

(14) Filed as an exhibit to the Company Registration Statement on Forms S-8 (File No. 33-61191) and incorporated herein by reference.
(15) Filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ended November 25, 1995 and incorporated herein by reference.
(16) Filed as an exhibit to the Company s 10-K for fiscal year ended August 31, 1996 and incorporated herein by reference.
(17) Filed as an exhibit to the Company s 10-Q/A for the quarter ended March 1, 1997 and incorporated herein by reference.
(18) Filed as exhibits to the Company s 10-Q for the quarter ended February 28, 1998 and incorporated herein by reference.
(19) Filed as exhibits to the Company s Registration Statement on Forms S-8 (333-49069) and incorporated herein by reference.
(20) Filed as an exhibit to the Company s 10-K for the fiscal year ended August 31, 1998 and incorporated herein by reference.
(21) Filed as an exhibit to the Company s 8-K filed on March 8, 2000 and incorporated herein by reference.
(22) Filed as an exhibit to the Company s 10-Q for the quarter ended November 27, 1999 and incorporated herein by reference.
(23) Filed as an exhibit to the Company s Registration Statement on Forms S-3 (333-32614) and incorporated herein by reference.
(24) Filed as an exhibit to the Company s Registration Statement on Form S-8 (333-58274) and incorporated herein by reference.
(25) Filed as an exhibit to the Company s 10-Q for the quarter ended February 24, 2001 and incorporated herein by reference.
(26) Filed as an exhibit to the Company s 10-Q for the quarter ended September 29, 2001 and incorporated herein by reference.
(27) Filed as an exhibit to the Company s 8-K filed on March 6, 2002 and incorporated herein by reference.
(28) Filed as an exhibit to the Company s 10-K for the fiscal year ended December 31, 2001 and incorporated herein by reference.
(29) Filed as an exhibit to the Company s 10-K/A2 for the fiscal year ended December 31, 2001 and incorporated herein by reference.
(30) Filed as an exhibit to the Company s 10-K/A for the fiscal year ended December 31, 2002 and incorporated herein by reference.
(31) Filed as an exhibit to the Company s 10-Q for the quarter ended March 29, 2003 and incorporated herein by reference.
(32) Filed as an exhibit to the Company s 8-K filed on June 5, 2003 and incorporated herein by reference.
(33) Filed as an exhibit to the Company s Registration Statement on Form S-8 (333-106563) and incorporated herein by reference
(34) Filed as an exhibit to the Company s 8-K filed on October 1, 2003 and incorporated herein by reference.
(35) Filed as an exhibit to the Company s 10-Q for the quarter ended September 27, 2003 and incorporated herein by reference.
(36) Filed as an exhibit to the Company s 8-K filed on November 18, 2003 and incorporated herein by reference.
(37) Filed as an exhibit to the Company s Registration Statement on Form S-4 (No. 333-111171) and incorporated herein by reference.
(38) Filed herewith.

SIGNATURES

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

GENOME THERAPEUTICS CORP.

By: /s/ STEVEN M. RAUSCHER

Steven M. Rauscher

President and Chief Executive Officer

Dated: March 5, 2004

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the date indicated.

/s/ STEVEN M. RAUSCHER **Steven Rauscher**	Director, President and Chief Executive Officer	March 5, 2004
/s/ STEPHEN COHEN **Stephen Cohen**	Senior Vice President and Chief Financial Officer (Chief Financial and Accounting Officer)	March 5, 2004
/s/ DAVID B. SINGER **David B. Singer**	Chairman of the Board and Director	March 5, 2004
/s/ LUKE EVNIN **Luke Evnin**	Director	March 5, 2004
/s/ ROBERT J. HENNESSEY **Robert J. Hennessey**	Director	March 5, 2004
/s/ VERNON R. LOUCKS, JR. **Vernon R. Loucks, Jr.**	Director	March 5, 2004
/s/ WILLIAM S. REARDON **William S. Reardon**	Director	March 5, 2004
/s/ NORBERT G. RIEDEL **Norbert G. Riedel**	Director	March 5, 2004
/s/ WILLIAM RUTTER	Director	March 5, 2004

	William Rutter		
/s/	DAVID K. STONE	Director	March 5, 2004
	David K. Stone		

GENOME THERAPEUTICS CORP. AND SUBSIDIARY

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

The Board of Directors and Stockholders of

Genome Therapeutics Corp.

We have audited the accompanying consolidated balance sheets of Genome Therapeutics Corp. as of December 31, 2003 and 2002, and the related consolidated statements of operations, consolidated statements of shareholders equity and comprehensive income, and consolidated statements of cash flows for the years 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 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 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 audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Genome Therapeutics Corp. at December 31, 2003 and 2002, and the consolidated results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States.

/s/ Ernst & Young LLP

Boston, Massachusetts

February 13, 2004

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, 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 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(l) as to which the

date is June 18, 2002)

GENOME THERAPEUTICS CORP. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2002	**2003**
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 11,128,507	$ 20,969,292
Marketable securities (held-to-maturity)	32,584,384	4,595,740
Marketable securities (available-for-sale)	3,585,550	3,100,000
Interest receivable	784,372	138,189
Accounts receivable	2,043,862	257,389
Unbilled costs and fees	714,468	78,899
Prepaid expenses and other current assets	444,402	41,953
Total current assets	51,285,545	29,181,462
Property and Equipment, at cost:		
Laboratory and scientific equipment	21,906,312	12,573,855
Leasehold improvements	8,923,916	7,516,159
Equipment and furniture	1,281,932	1,240,682
	32,112,160	21,330,696
Less Accumulated depreciation	21,973,715	18,009,495
	10,138,445	3,321,201
Long-term Marketable Securities (held-to-maturity)	3,567,757	
Note Receivable-Related Party (Note 5)		6,238,219
Other Assets	853,387	1,775,433
	$ 65,845,134	$ 40,516,315
LIABILITIES AND SHAREHOLDERS EQUITY		
Current Liabilities:		
Current maturities of long-term obligations	$ 2,623,986	$ 1,166,667
Accounts payable	2,175,047	1,523,633
Accrued expenses (Note 14)	4,079,148	3,483,308
Clinical trial expense accrual	4,329,792	3,652,604
Deferred revenue	1,566,145	458,333
Total current liabilities	14,774,118	10,284,545
Long-term Obligations, net of current maturities	15,654,292	291,666
Commitments (Note 7 and 11)		
Shareholders Equity:		
Common stock, $0.10 par value Authorized 50,000,000 shares, Issued and outstanding 23,066,072 and 31,479,650 shares in 2002 and 2003, respectively	2,306,607	3,147,965
Additional paid-in capital	158,976,618	182,727,198
Accumulated deficit	(125,775,400)	(155,564,152)
Deferred compensation and note receivable from officer (Note 9(d))	(376,490)	(370,907)
Accumulated other comprehensive income	285,389	

Total shareholders equity	35,416,724	29,940,104
	$ 65,845,134	$ 40,516,315

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

GENOME THERAPEUTICS CORP. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2001	**2002**	**2003**
Revenues:			
Biopharmaceutical	$ 18,438,286	$ 7,715,992	$ 7,009,175
Genomics services	17,302,239	15,270,863	2,049,438
Total revenues	35,740,525	22,986,855	9,058,613
Costs and Expenses:			
Cost of services	16,139,988	15,040,606	1,902,561
Research and development	24,041,426	32,465,841	22,163,080
Selling, general and administrative	8,767,229	9,381,931	7,403,540
Restructuring charge			5,257,262
Convertible debt retirement expense			5,540,333
Total costs and expenses	48,948,643	56,888,378	42,266,776
Loss from operations	(13,208,118)	(33,901,523)	(33,208,163)
Other Income (Expense):			
Interest income	3,839,260	1,768,690	580,792
Interest expense	(692,391)	(1,936,117)	(990,399)
(Loss) gain on sale of fixed assets	(29,053)	51,925	183,406
Other income (Note 1(j) and 3(b))			3,645,612
Net other income (expense)	3,117,816	(115,502)	3,419,411
Net loss	$ (10,090,302)	$ (34,017,025)	$ (29,788,752)
Net Loss per Common Share:			
Basic and diluted	$ (0.45)	$ (1.48)	$ (1.13)
Weighted Average Common Shares Outstanding:			
Basic and diluted	22,572,427	22,920,875	26,289,876

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

GENOME THERAPEUTICS CORP. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY AND COMPREHENSIVE INCOME

	Common Stock				Deferred Compen-sation & Note		Total	
	Shares	$0.10 Par Value	Additional Paid-In Capital	Accumulated Deficit	Receivable From Officer	Accumulated Other Comprehensive Income	Share-holders Equity	Compre-hensive Income
Balance, December 31, 2000	22,288,658	$ 2,228,866	$ 152,723,288	$ (81,668,073)	$ (596,629)	$	$ 72,687,452	$ (5,846,839)
Sale of common stock, net of issuance costs of $44,622	127,500	12,750	1,693,017				1,705,767	
Exercise of stock options	251,354	25,135	736,584				761,719	
Issuance of stock under employee stock purchase plan	74,596	7,460	434,410				441,870	
Issuance of restricted common stock and loan to officer (Note 6e)	24,000	2,400	(2,400)		(163,000)		(163,000)	
Deferred compensation from grant of stock options			647,942		(647,942)			
Issuance of stock under directors deferred stock plan	6,062	606	(606)					
Amortization of deferred compensation and other stock-based compensation expense					883,983		883,983	
Reversal of deferred compensation related to cancellation of stock options			(17,500)		17,500			
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)
Net loss				(10,090,302)			(10,090,302)	(10,090,302)
Balance, December 31, 2001	22,772,170	2,277,217	156,214,735	(91,758,375)	(506,088)	504,449	66,731,938	(9,585,853)
Exercise of stock options	10,614	1,061	11,987				13,048	
Issuance of stock under employee stock purchase plan	143,462	14,346	438,587				452,933	
Issuance of stock related to interest payable under convertible notes	120,986	12,099	276,394				288,493	
Deferred compensation from grant of stock options			300,740		(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					430,338		430,338	
Value of warrants issued in connection with convertible notes			1,736,059				1,736,059	
Unrealized loss on short-term investment (available for sale)						(249,890)	(249,890)	(249,890)
						30,830	30,830	30,830

Reversal of unrealized loss on derivative instruments								
Net loss				(34,017,025)			(34,017,025)	(34,017,025)
Balance, December 31, 2002	23,066,072	$ 2,306,607	$ 158,976,618	$ (125,775,400)	$ (376,490)	$ 285,389	$ 35,416,724	$ (34,236,085)
Sale of common stock, net of issuance costs of $899,836	5,366,333	536,633	12,113,531				12,650,164	
Exercise of stock options	336,962	33,696	465,091				498,787	
Issuance of stock related to the retirement of convertible notes	1,946,586	194,659	8,817,610				9,012,269	
Issuance of stock related to interest payable under convertible notes	422,705	42,271	538,825				581,096	
Issuance of stock under employee stock purchase plan	339,827	33,982	419,517				453,499	
Deferred compensation from grant of stock options			818,911		(818,911)			
Issuance of stock under directors deferred stock plan	1,165	117	(117)					
Amortization of deferred compensation and other stock-based compensation expense					816,995		816,995	
Reversal of deferred compensation related to cancellation of stock options			(7,499)		7,499			
Reversal of unrealized gain on long-term investment (available for sale)						(285,389)	(285,389)	(285,389)
Proceeds from a legal claim with an investor		584,711					584,711	
Net loss				(29,788,752)			(29,788,752)	(29,788,752)
Balance, December 31, 2003	31,479,650	$ 3,147,965	$ 182,727,198	$ (155,564,152)	$ (370,907)	$	$ 29,940,104	$ (30,074,141)

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

GENOME THERAPEUTICS CORP. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2001	**2002**	**2003**
Cash Flows from Operating Activities:			
Net loss	$ (10,090,302)	$ (34,017,025)	$ (29,788,752)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	4,807,379	5,544,813	2,545,414
Non-cash restructuring charge			3,749,741
Non-cash convertible debt retirement expense			4,012,269
Non-cash interest expense		510,605	1,225,454
Loss (gain) on disposal of equipment and leasehold improvements	29,053	(51,926)	(183,406)
Amortization of deferred compensation	883,983	430,338	816,995
Changes in assets and liabilities			
Interest receivable	392,082	290,354	646,183
Accounts receivable	313,221	(1,529,977)	1,786,473
Unbilled costs and fees	631,607	(550,003)	635,569
Prepaid expenses and other current assets	(682,773)	1,138,918	402,449
Accounts payable	796,082	82,454	(651,414)
Accrued expenses	(197,198)	852,082	(14,744)
Clinical trial expense accrual	1,286,324	3,043,468	(677,188)
Deferred revenue	(1,270,275)	(1,883,814)	(1,107,812)
Net cash used in operating activities	(3,100,817)	(26,139,713)	(16,602,769)
Cash Flows from Investing Activities:			
Purchases of marketable securities	(48,676,465)	(37,830,976)	(8,323,011)
Proceeds from sale of marketable securities	68,439,950	42,179,260	40,079,573
Purchases of property and equipment	(3,705,719)	(3,817,612)	(121,177)
Proceeds from sale of property and equipment	10,302	79,807	826,671
Decrease in restricted cash		200,000	
Increase in notes receivable			(6,238,219)
Decrease (increase) in other assets	47,616	(684,962)	(922,046)
Net cash provided by investing activities	16,115,684	125,517	25,301,791
Cash Flows from Financing Activities:			
Proceeds from sale of common stock	1,705,767		12,650,164
Proceeds from exercise of stock options	761,719	13,048	498,787
Proceeds from issuance of stock under the employee stock purchase plan	441,870	452,933	453,499
Note receivable from officer	(163,000)		
Gross proceeds from convertible notes payable		15,000,000	
Proceeds from borrowings on equipment financing arrangements	2,761,441	3,500,000	
Proceeds from a legal claim with an investor			584,711
Payments made upon retirement of convertible notes payable			(10,000,000)
Payments on long-term obligations	(4,963,096)	(4,628,663)	(3,045,398)
Net cash provided by financing activities	544,701	14,337,318	1,141,763
Net Increase (Decrease) in Cash and Cash Equivalents	13,559,568	(11,676,878)	9,840,785
Cash and Cash Equivalents, beginning of year	9,245,817	22,805,385	11,128,507
Cash and Cash Equivalents, end of year	$ 22,805,385	$ 11,128,507	$ 20,969,292

Supplemental Disclosure of Cash Flow Information:			
Interest paid during the year	$ 692,391	$ 1,131,725	$ 562,922
Income taxes paid during the year	$ 60,000	$ 50,004	$ 30,000
Supplemental Disclosure of Non-cash Investing and Financing Activities:			
Equipment acquired under capital leases	$ 2,761,441	$	$
Issuance of warrant in connection with convertible notes payable	$	$ 1,736,059	$ 149,781
Issuance of common stock upon retirement of convertible notes payable	$	$	$ 5,000,000

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

GENOME THERAPEUTICS CORP. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(1) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Genome Therapeutics and subsidiary (the Company) is a biopharmaceutical company committed to the clinical development and commercialization of important new therapeutics to serve unmet medical needs. On February 6, 2004, the Company completed its merger with Genesoft Pharmaceuticals Inc. (Genesoft), a privately-held pharmaceutical company based in South San Francisco, California. The Company s product portfolio is now led by the FDA-approved fluoroquinolone antibiotic FACTIVE (gemifloxacin mesylate) tablets, indicated for the treatment of community-acquired pneumonia of mild-to-moderate severity and acute bacterial exacerbations of chronic bronchitis.

In addition, the Company is developing a novel antibiotic candidate, Ramoplanin, which is currently in clinical trials for the prevention and treatment of serious hospital-acquired infections. Ramoplanin is in a Phase III trial for the prevention of bloodstream infections caused by vancomycin-resistant enterococci and in a Phase II trial for the treatment of *Clostridium difficile*-associated diarrhea.

The Company s preclinical development programs include an oral peptide deformylase inhibitor series for the potential treatment of respiratory tract infections as well as development of a FACTIVE intravenous formulation. We also have six pharmaceutical alliances focused on the development of novel therapeutics and diagnostics for chronic human diseases and certain infectious diseases. These alliances were formed in previous years based on our genomics drug discovery expertise. Our business strategy has shifted away from gene discovery and partnerships of this type to focus on development and commercialization of our own products.

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 government research grants and license fees, contract research and milestone payments from alliances with pharmaceutical companies. Genomics services revenues consist of government sequencing grants, fees and royalties received from custom gene sequencing and analysis services and subscription fees from the PathoGenome™ Database.

Revenues from contract research, government grants, 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. The percentage of services performed related to contract research, government grants and custom gene sequencing and analysis services is based on the ratio of the number of direct labor hours performed to date to total direct labor hours the Company is obligated to perform under the related contract, as determined on a full-time equivalent basis. Revenues from PathoGenome™ Database subscription fees are recognized ratably over the term of the subscription agreement.

GENOME THERAPEUTICS CORP. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Amounts received for license fees are deferred and recognized ratably over the performance period in accordance with Staff Accounting Bulletin (SAB) No. 104, Revenue Recognition . Milestone payments will be recognized upon achievement of the milestone as long as the milestone is nonrefundable, deemed to be substantive and the Company has no other performance obligations related to the milestone. Unbilled costs and fees represent revenue recognized prior to billing. Deferred revenue represents amounts received prior to revenue recognition.

(c) Clinical Trial Expense Accrual

The Company s clinical development trials related to Ramoplanin are primarily performed by outside parties. It is not unusual at the end of each accounting period for the Company to estimate both the total cost and time period of the trials and the percent completed as of that accounting date. The Company also adjust these estimates when final invoices are received. During 2003, the Company adjusted its accrual for clinical trial expenditures to reflect its most current estimate of liabilities outstanding to outside parties, resulting in a favorable change in estimate in the accrual for clinical development expenditures. The Company believes that the estimates that the Company made as of December 31, 2003 are reflective of the actual expenses incurred as of that date. However, readers should be cautioned that the possibility exists that the timing or cost of the Ramoplanin clinical trials might be longer or shorter and cost more or less than the Company has estimated and that the associated financial adjustments would be reflected in future periods.

For the clinical development of Ramoplanin, the Company recorded an expense of approximately $5,556,000, $13,895,000 and $10,798,000 during the years ending December 31, 2001, 2002 and 2003, respectively, which consisted of initial license fee, milestone payment and clinical development expenses. December 31, 2003 includes a favorable change in estimate in the accrual for clinical development expenditures.

(d) Property and Equipment

The Company records property, plant and equipment at cost. The Company depreciates its property 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.

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

Depreciation expense was approximately $4,807,000, $5,545,000 and $2,545,000 for the years ended December 31, 2001, 2002, and 2003, respectively.

(e) 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 3,746,794, 5,322,897 and 7,366,337 shares during the years ended December 31, 2001, 2002 and 2003, respectively.

GENOME THERAPEUTICS CORP. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(f) 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:

	Number of Significant	Percentage of Total Revenues				
Year ended December 31,	Customers	A	B	C	D	E
2001	3	31%	36%	18%		
2002	2	23%	46%			
2003	4		16%	12%	14%	46%

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:

	Percentage of Total Accounts Receivable					
At December 31,	B	E	F	G	H	I
2001					37%	29%
2002	23%	37%	27%			
2003	21%			64%		

(g) 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.

(h) 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.

(i) Reclassifications

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

GENOME THERAPEUTICS CORP. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(j) 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. Historically, other comprehensive income had included net loss and change in unrealized gains and losses in marketable securities. 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 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. In 2003, these common shares were sold through the Nasdaq National Market and the Company recorded a realized gain of approximately $608,000 related to this transaction.

(k) 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 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 views its operations and manages its business as principally two operating segments: genomics services and biopharmaceutical. As a result, the financial information disclosed herein represents all of the material financial information related to the Company s two operating segments. All of the Company s revenues are generated in the United States and all assets are located in the United States.

	Genomics Services	Biopharmaceutical	Total
2001			
Revenues	$ 17,302,239	$ 18,438,286	$ 35,740,525
Gross profit	1,162,251	11,129,357	12,291,608
Company-funded research & development		16,732,497	16,732,497
2002			
Revenues	$ 15,270,863	$ 7,715,992	$ 22,986,855
Gross profit	230,257	2,467,477	2,697,734
Company-funded research & development		27,217,326	27,217,326
2003			
Revenues	$ 2,049,438	$ 7,009,175	$ 9,058,613
Gross profit	146,877	1,992,399	2,139,276
Company-funded research & development		17,146,304	17,146,304

The Company does not allocate assets by its operating segments.

GENOME THERAPEUTICS CORP. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(l) Recent Accounting Pronouncements

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity . SFAS No. 150 establishes how a company classifies and measures certain financial instruments with characteristics of both liabilities and equity, including redeemable convertible preferred stock. This statement is effective for financial instruments entered into or modified after May 31, 2003, and is otherwise effective at the beginning of the interim period commencing July 1, 2003, except for mandatory redeemable financial instruments of nonpublic companies. The FASB has indefinitely deferred implementation of some provisions of SFAS No. 150. The Company believes that the adoption of SFAS No. 150 will not have a material effect on our financial position or results of operations.

In January 2003, the FASB, issued FIN No. 46, Consolidation of Variable Interest Entities , which FIN No. 46 sets forth the criteria used in determining whether an investment in a variable interest entity, or VIE, should be consolidated and is based on the general premise that companies that control another entity through interests other than voting interests should consolidate the controlled entity. FIN No. 46 would require the consolidation of specified VIE s created before February 1, 2003 in the Company s Annual Report on Form 10-K for the year ended December 31, 2003. For specified VIE s created after January 31, 2003, FIN No. 46 would require consolidation in this Annual Report on Form 10-K. As of December 31, 2003, the Company does not have an interest in any VIE s. Accordingly, the implementation of FIN No. 46 will not have any impact on the Company s consolidated financial statements.

(m) Pro Forma Disclosure of Stock-based Compensation

The Company follows Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees (APB25) 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 these plans equals the market price of the underlying stock on the date of grant, no compensation expense is required. Under APB 25, when the exercise price of options granted under these plans is less than the market price of the underlying stock on the date of grant, the difference is recorded as deferred compensation and recognized as expense on a straight line basis over the vesting period of the option. In accordance with Emerging Issues Task Force Issue No. 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.

	2001	2002	2003
Risk-free interest rate	4.31% 5.24%	3.50% 5.14%	3.07% 3.96%
Expected dividend yield			

Expected life	5 years	5 years	5 years
Expected volatility	87%	84%	83%
Weighted average grant date fair market value	$6.25	$1.83	$1.22

GENOME THERAPEUTICS CORP. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	2001	2002	2003
Net loss as reported	$ (10,090,302)	$ (34,017,025)	$ (29,788,752)
Add: Stock-based employee compensation cost, included in the determination of net loss as reported	883,983	430,338	816,995
Less: Total stock-based compensation cost determined under fair value based method for all employee awards	(7,494,633)	(4,936,526)	(2,452,711)
Pro forma net loss	$ (16,700,952)	$ (38,523,213)	$ (31,424,468)
Basis and diluted net loss per share			
As reported	$ (0.45)	$ (1.48)	$ (1.13)
Pro forma	$ (0.74)	$ (1.68)	$ (1.20)

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 2001, 2002, and 2003 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.

(2) RESTRUCTURING PLAN

As part of our effort to reduce costs and expenses, the Company adopted a plan in 2003 to substantially reduce its research effort in internally funded early-stage drug discovery programs under its biopharmaceutical operating segment. Under this plan, the Company eliminated 33 full-time positions and recorded a restructuring charge in the statements of operations in 2003. The following table displays the restructuring activity and liability balance included in accrued expenses.

	Year Ended December 31, 2003					
	Balance at December 31, 2002	Charges	Cash Payments	Asset Impairment	Stock Option Compensation	Balance at December 31, 2003
Termination benefits	$	$ 1,507,521	$ (708,489)	$	$ (186,791)	$ 612,241
Asset impairment		3,749,741		(3,749,741)		
	$	$ 5,257,262	$ (708,489)	$ (3,749,741)	$ (186,791)	$ 612,241

Costs of termination benefits relate to severance packages, outplacement services and a non-cash charge for the acceleration of vesting of previously granted stock options for employees affected by the initiative. The remaining termination benefits will be paid out during the first seven months of 2004. The Company s decision to terminate certain research programs and to vacate laboratory space were deemed to be impairment indicators under SFAS No. 144, Accounting for Impairment of Disposal of Long-Lived Assets . As a result of performing the impairment evaluations, asset impairment charges were recorded during the second quarter of 2004 to adjust the carrying value of the related long-lived assets to their net realizable value. During 2003, the Company sold a portion of these long-lived assets and recorded a gain of approximately $310,000. At December 31, 2003, the net realized value of the remaining long-lived assets on hand was approximately $397,000. The Company plans to sell these assets over the next twelve months.

GENOME THERAPEUTICS CORP. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(3) SALE OF GENOMICS SERVICES AND INTELLECTUAL PROPERTY

(a) Sale of Genomics Services

Genomics services revenue consists of government sequencing grants, fees and royalties received from custom gene sequencing and analysis, and subscription fees from the PathoGenome™ Database.

On March 14, 2003, the Company completed the sale of its genomics services business to Agencourt Bioscience Corporation (Agencourt). As part of the Asset Purchase Agreement (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 of $200,000 and shares of Agencourt common stock. The Company will also receive royalties on gene sequencing revenue earned by Agencourt that is related to the transferred business for a period of two years after the date of sale. The Company retains rights to its PathoGenome™ Database, including all associated intellectual property, subscriptions and royalty rights on products developed by subscribers.

As discussed above, the Company will receive royalties on gene sequencing revenue earned by Agencourt that is related to the transferred business for a period of two years after the date of sale. Accordingly, the cash flows from the genomics services group will not have been completely eliminated from the ongoing operations of the Company as a result of the disposal transaction. As a result, the sale does not initially qualify as a discontinued operation as defined by SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets . As of December 31, 2003, the Company has recognized approximately $584,000 in royalties from Agencourt.

In connection with the sale of its genomics services business, the Company determined that certain equipment related to this segment would no longer be used and would 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, which is included in research and development expenditures during the fourth quarter of 2002. The Company also evaluated and wrote down its excess inventory of disposables related to the genomics services business by $312,000 during the fourth quarter of 2002. Additionally, through this divestiture, the Company eliminated approximately 60 full-time positions, of which approximately 49 employees were not offered employment with Agencourt. The Company recorded a charge of approximately $691,000 in 2003, of which approximately $127,000 was related to the transfer of assets to Agencourt and approximately $564,000 associated with the reduction in work force, such as severance costs and outplacement services. As of December 31, 2003, all payments related to both severance and outplacement services from genomics services employees have been made.

(b) Sale of Intellectual Property

In December 2003, the Company sold its pending applications related to the organism *Streptococcus pneumoniae* to Aventis Pasteur for a one-time cash payment of $3,000,000. The Company has recorded the gain on the sale as other income in its Consolidated Statements of Operations for the year ended December 31, 2003.

(4) 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, 2002 and 2003, the Company s investments included primarily 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 2.1 months at December 31, 2003.

GENOME THERAPEUTICS CORP. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

At December 31, 2003, the Company s short-term marketable securities (held-to-maturity) included shares of common stock of Agencourt received in connection with the Agreement dated March 14, 2003. Such investments are carried at cost which approximates market value.

At December 31, 2002 and 2003, the Company s short-term marketable securities also included taxable auction securities which are classified as available-for-sale securities and were recorded at fair value. Additionally, the Company s short-term marketable securities (available-for-sale) at December 31, 2002 included 45,000 shares of common stock of Vicuron which was received in connection with its collaboration agreement dated March 10, 1997. These shares were recorded at fair value. The Company sold these shares in 2003 and recorded a realized gain of $608,000.

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

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Loss	Estimated Fair Value
December 31, 2002				
Cash:	$ 11,128,507	$	$	$ 11,128,507
Investments (held-to-maturity):				
Short-term marketable securities	$ 32,584,384	$ 89,220	$ (3,067)	$ 32,670,537
Long-term marketable securities	3,567,757	14,311	(1,862)	3,580,206
Total investments	$ 36,152,141	$ 103,531	$ (4,929)	$ 36,250,743
Investments (available-for-sale):				
Short-term marketable securities	$ 3,300,160	$ 285,390	$	$ 3,585,550
December 31, 2003				
Cash and Cash Equivalents:				
Cash	$ 17,208,907	$	$	$ 17,208,907
Debt securities	3,760,335	325	(1,335)	3,759,375
Total cash and cash equivalents	$ 20,969,292	$ 325	$ (1,335)	$ 20,968,282
Investments (held-to-maturity):				
Short-term marketable securities	$ 4,595,740	$ 692	$ (2,985)	$ 4,593,447
Investments (available-for-sale):				
Short-term marketable securities	$ 3,100,000	$	$	$ 3,100,000

(5) NOTE RECEIVABLE

At the time of the signing of the merger agreement with Genesoft on November 17, 2003, the Company made a bridge loan of $6.2 million with an interest rate of 5% per annum to Genesoft pursuant to a promissory note. This note receivable and related interest owed was assumed in the merger and accordingly, included in the purchase price of this merger transaction (See Note 15).

GENOME THERAPEUTICS CORP. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(6) 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, 2003, the Company had net operating loss carryforwards of approximately $144,170,000 and $120,939,000 available to reduce federal and state taxable income, respectively, if any. The Company also had tax credit carryforwards of approximately $12,240,000 to reduce federal income tax, 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%. Additionally, certain losses have begun to expire due to the limitations of the carryforward.

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

Expiration Date	Federal Net Operating Loss Carryforwards	State Net Operating Loss Carryforwards	Research Tax Credit Carryforwards	Investment Tax Credit Carryforwards
2004	$	$ 8,515,000	$	$
2005		35,624,000	80,000	101,000
2006	1,808,000	8,990,000	208,000	4,000
2007	2,206,000	10,513,000	274,000	
2008-2024	140,156,000	57,297,000	11,573,000	
	$ 144,170,000	$ 120,939,000	$ 12,135,000	$ 105,000

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

	December 31,	
	2002	2003
Net operating loss carryforwards	$ 48,448,000	$ 55,850,000

Research and development credits	9,047,000	10,489,000
Investment tax credits	37,000	69,000
Capitalized research & development costs	4,897,000	4,267,000
Depreciation	1,459,000	2,760,000
Warrants		759,000
Other temporary differences	1,783,000	1,062,000
Net deferred tax asset	65,671,000	75,256,000
Valuation allowance	(65,671,000)	(75,256,000)
	$	$

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

GENOME THERAPEUTICS CORP. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(7) COMMITMENTS

(a) Lease Commitments

The Company leases its office facilities under an operating lease arrangement which expires on November 15, 2006 and had an operating lease for certain computer equipment which expired in January 2003. Rental expense under these operating leases was approximately $1,007,000, $1,020,000 and $1,079,000 for the years ended December 31, 2001, 2002 and 2003, respectively. A portion of the leased facilities has been subleased to external parties in December 2003. Rental income under these subleases which is an offset to rental expense was approximately $11,000 in 2003. The aggregate future minimum rental to be received under the subleases amounts to approximately $999,000 at December 31, 2003 and is due through November 15, 2006.

The future minimum lease payments and facilities charges under the operating leases (gross of sublease income) at December 31, 2003 are as follows:

Year ending December 31,	
2004	$ 761,000
2005	739,000
2006	747,000
	$ 2,247,000

(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.

(8) 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 were convertible 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 was December 31, 2004. Interest on the convertible notes payable accrued at 6% annually and the interest was payable, in cash or in stock, semi-annually on June 30 and

December 31 of each year. 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 was exercisable at the time the convertible notes payable were converted or if certain other redemptions or repayments of the convertible notes payable occurred and terminated upon the earlier of four years from the date of such conversion or December 31, 2008. The warrant was valued, using the Black-Scholes option pricing model, at approximately $1,736,000. The amount was recorded as a discount to long-term obligations and 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. As of December 31, 2003, this warrant had not been issued.

On June 4, 2003, the Company entered into an Amendment, Redemption and Exchange Agreement with the two institutional investors providing for (i) the redemption in cash of a portion of the 6% Convertible Notes due December 31, 2004, (ii) the conversion of the remaining portion of the convertible notes into common stock of the Company and (iii) the issuance to the investors of new warrants in exchange for warrants previously issued to the investors.

GENOME THERAPEUTICS CORP. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Under the terms of the agreement, the Company redeemed an aggregate of $10,000,000 in principal amount of the convertible notes for a cash payment of $10,000,000 to the investors, and the related accrued and unpaid interest on such principal amount of the convertible notes for a cash payment of an aggregate of $254,795 to the investors. The conversion price of the remaining $5,000,000 in principal amount of the convertible notes was amended to equal $2.5686 per share and the investors converted the remaining amount of the convertible notes, plus related accrued and unpaid interest, into 1,996,184 shares of the Company s common stock. The Company also issued new warrants in exchange for the warrants that were previously issued to the investors. The new warrants have a term of five years from the issuance date, are immediately exercisable and allow the investors to purchase in the aggregate up to 535,806 shares of the Company s common stock at an exercise price of $3.37 per share. The new warrants include provisions for adjustment of the exercise price and the number of shares issuable upon exercise in the event of stock splits, stock dividends, reverse stock splits, and issuances by the Company of shares of its capital stock at prices below the exercise price or the fair market value of the common stock if higher than such exercise price. The Company had also granted the investors a right of participation to purchase up to 33.33% of the amount of securities sold to investors in non-registered or shelf capital raising transactions (subject to certain exceptions), provided that if any such transaction exceeds $15,000,000, then for the portion of the transaction that exceeds $15,000,000, the investors have the right to purchase up to 20% of such excess amount sold to investors. In addition, each investor has the right to purchase at least $1,000,000 of securities in any such transaction. The rights described in this paragraph are effective until the second anniversary of the closing date of the transaction.

The Company applies the provisions of SFAS No. 84, Induced Conversions of Convertible Debt and Emerging Issues Task Force Issue No. 02-15, Determining Whether Certain Conversion of Convertible Debt to Equity Securities Are Within the Scope of FASB Statement No. 84 . SFAS 84 specifies the method of accounting for conversions of the convertible debt to equity securities when the debtor induces conversion of the debt by offering additional securities or other consideration to convertible debt holder. In 2003, the Company recorded a one-time charge to convertible debt retirement expense of $5,540,000, which consisted of $3,862,000 for the fair value of the incremental shares issued under the new agreement, $150,000 for the incremental fair value of the exchange warrants using the Black-Scholes option pricing model, as well as $574,000 of unamortized closing costs related to the original agreement and $954,000 of unamortized cost related to the value of the original warrants.

In February 2002, the Company entered into a loan agreement for $3,500,000, of which $500,000 was used to refinance a portion of an existing line of credit. This loan is payable in twelve consecutive quarterly payments at the prevailing LIBOR rate (1.21% at December 31, 2003) plus 1.50%. The Company is required to maintain certain financial covenants pertaining to minimum cash balances. As of December 31, 2003, $1.5 million was outstanding under the loan agreement, and the Company was in compliance with all of the covenants.

Minimum payments under long-term obligations at December 31, 2003 are as follows:

Year ending December 31,	
2004	$ 1,201,667
2005	291,666
Total minimum payments	1,493,333
Less Amount representing interest	35,000
Present value of total minimum payments	1,458,333
Less Current portion	1,166,667

	$ 291,666

GENOME THERAPEUTICS CORP. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(9) 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 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 2001, 2002 and 2003, the Company recorded $647,942, $300,740 and $818,911, respectively, of deferred compensation. The Company recorded amortization of deferred compensation of approximately $883,983, $430,338 and $816,995 for the years ended December 31, 2001, 2002 and 2003, respectively.

There were 1,353,160 common shares available for future grant at December 31, 2003. The following is a summary of all stock option activity:

	Number of Shares	Exercise Price Range	Weighted Average Price
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
Granted	709,423	0.38-2.97	0.94
Exercised	(336,962)	0.51-2.40	1.48
Cancelled	(803,642)	0.51-66.00	6.31
Outstanding, December 31, 2003	4,045,346	$ 0.10-49.91	$ 5.94

Exercisable, December 31, 2003	2,489,952	$ 0.10-49.91	$ 6.86
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

GENOME THERAPEUTICS CORP. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The range of exercise prices for options outstanding and options exercisable at December 31, 2003 are as follows:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Weighted Average Remaining Contractual Life of Options Outstanding (In Years)	Number	Weighted Average Exercise Price	Number	Weighted Average Exercise Price
$ 0.10 3.00	6.74	1,914,540	$ 1.36	968,292	$ 1.42
$ 3.13 5.65	6.73	495,365	4.57	316,490	4.31
$ 6.01 8.87	4.48	632,401	8.06	492,442	8.25
$ 9.93 11.76	7.38	203,500	10.95	85,875	11.55
$ 12.29 14.72	6.83	759,540	14.47	596,665	14.48
$ 15.97 49.91	6.53	40,000	21.63	30,188	21.65
Total	6.43	4,045,346	$ 5.94	2,489,952	$ 6.86

(b) Sale of Common Stock

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

In September and October 2003, the Company completed a private placement of 5,220,000 shares of common stock at $2.50 per share resulting in proceeds of approximately $12,150,000, net of issuance costs of $899,836. In connection with this private placement, the Company issued warrants to purchase 2,610,000 shares of common stock at an exercise price of $3.48 per share, subject to certain adjustments. These warrants remain exercisable for a period of five years and cannot be exercised during the six-month period immediately following the transaction.

(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 and will be issued three-years from the date of grant or earlier if the individual ceases to serve as a member of the Company s Board of Directors. The Company granted 71,570 shares of restricted common stock under this plan, of which 26,867 were issued. In April 2003, the Company terminated the 1997 Directors Plan and exchanged 44,703 shares of unissued restricted common stock for 63,861 shares of vested stock options at an exercise price of $0.51. No additional shares will be issued under this plan.

(d) Note Receivable from Officer

In March 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.

GENOME THERAPEUTICS CORP. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(e) Employee Stock Purchase Plan

In February 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, 2003, the Company has issued 566,216 shares under this plan.

(f) Proceeds from Legal Claim

In June 2003, the Company received approximately $584,000, net of legal costs, from a settlement of a claim with an investor. This amount was recorded within Stockholders Equity as it relates to proceeds received from a shareholder.

(10) 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 $251,157, $283,718 and $201,751 to the Plan for the years ended December 31, 2001, 2002 and 2003, respectively.

(11) PRODUCT DEVELOPMENT

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

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

GENOME THERAPEUTICS CORP. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(12) RESEARCH AND DEVELOPMEMT AND ALLIANCES

Research and development expenses primarily consist of salaries and related expenses for personnel and the cost of materials used in sequencing activities and research and development. Other research and development expenses include fees paid to consultants and outside service providers, information technology and facilities costs. The Company charges all research and development expenses to operations as incurred. The research and development efforts performed for the Company s alliance partners generally consist of sequencing services and related research activities. The Company s revenue recognition policy for the funding received for these services and research activities is disclosed in the Company s policy discussed in Note 1(b). The Company has generally been compensated for its research and development efforts by its alliance partners on a full-time equivalent basis. Accordingly, the services provided to the Company s alliance partners are generally limited to the performance of a specified number of hours of research. As a result, the Company manages the research efforts related to the Company s alliances through an analysis of direct labor hours and the consideration received on a per full-time equivalent basis.

The Company does not track actual costs related to each of its alliances or its internal research and development programs and as a result, this information is not available. The Company does, however, track total costs in the aggregate for its alliance arrangements separately from its internal research and development programs. The Company incurred approximately $7,309,000, $5,249,000 and $5,017,000 related to its alliances for the years ended December 31, 2001, 2002 and 2003, respectively.

The Company has entered into the alliances described below with biopharmaceutical partners in order to discover, research, develop and commercialize products. Potential revenues (exclusive of royalty payments earned upon the successful commercialization of products) to be earned by the Company generally include an upfront license fee, sponsored /contract research payments and research and development and regulatory approval milestone payments. In the alliances summarized below, a portion of the total potential alliance revenues has already been earned with described future payments potentially yet to be realized. Those future payments are earned primarily through the achievement of research, development and regulatory approval milestones. The Company s ability to earn those future milestone payments depends primarily upon whether our alliance partner identifies any compounds, through high-throughput screening and lead optimization, that warrant clinical development, whether any such compounds demonstrate the required safety and efficacy in clinical trials in order to support a regulatory approval and whether they are able to successfully manufacture and commercialize the product. It is uncertain whether we will earn those milestone payments due to numerous factors, including the risk of failure inherent in complex research and development programs, potential delays in clinical trials, negative, inconclusive or insufficient clinical data or the emergence of superior competitor products that may lead to abandonment of the program. The Company has not recognized any royalty revenue to date under these arrangements.

Except for the Amgen arrangement, the Company has completed its research obligations in connection with the following alliances. Consequently, receipt of future revenues from such alliances is dependent upon the alliance partner furthering the research and commercial activity related to the licensed technology.

(a) ASTRAZENECA

In August 1995, the Company entered into a strategic alliance with AstraZeneca, formerly Astra Hassle AB, to develop drugs, vaccines and diagnostic products effective against peptic ulcers or any other disease caused by *H. pylori*. 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.

GENOME THERAPEUTICS CORP. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Under this agreement, AstraZeneca agreed to pay the Company, subject to the achievement of certain product development milestones, up to $23.5 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 AstraZeneca agreement through December 31, 2003. The Company will also be entitled to receive royalties on AstraZeneca s sale of certain products licensed to AstraZeneca by the Company pursuant to the agreement. In its development of new anti-ulcer products, AstraZeneca has selected a novel lead series for advancement into lead optimization.

The Company recognized approximately $0, $172,000 and $0 in revenue under this agreement during the years ended December 31, 2001, 2002 and 2003, 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 *Staphylococcus aureus* to identify and validate new gene targets for development of drugs to target *S. aureus* and other pathogens that have become resistant to current antibiotics.

Under this agreement, Schering-Plough paid an initial license fee and funded a research program through March 31, 2002. Schering-Plough paid the Company $21.4 million in an up-front license fee, research funding and milestone payments through December 31, 2003. Subject to the achievement of additional product development milestones, Schering-Plough agreed to pay the Company up to an additional $24.0 million in milestone payments.

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 $1,570,000, $127,000 and $0 revenues during the years ended December 31, 2001, 2002 and 2003, respectively.

In December 1996, the Company entered into its second strategic alliance and license agreement (the December 1996 agreement) with Schering-Plough. This agreement calls for the use of genomics to discover new pharmaceutical products for treating asthma. Under this agreement, the Company has granted Schering-Plough 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 the December 1996 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

GENOME THERAPEUTICS CORP. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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. A total of $42.5 million has been received through December 31, 2003.

Under this agreement, the Company recognized approximately $8,084,000, $5,088,000 and $115,000 in revenue during the years ended December 31, 2001, 2002 and 2003, respectively.

In September 1997, the Company entered into a third strategic alliance and license agreement (the September 1997 agreement) with Schering-Plough to use genomics to discover and develop new pharmaceutical products to treat fungal infections. Under this agreement, the Company granted Schering-Plough 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 funded 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. A total of $12.2 million has been received through December 31, 2003.

Under the September 1997 agreement, the Company recognized approximately $1,137,000, $6,000 and $0 in revenue for the years ended December 31, 2001, 2002 and 2003, respectively.

(c) BIOMÉRIEUX

In September 1999, the Company entered into a strategic alliance with bioMérieux to develop, manufacture and sell *in vitro* diagnostic products for human clinical and industrial applications. As part of the alliance, bioMérieux purchased a subscription to the Company s PathoGenome™ Database, paid an up-front license fee, funded a research program for four years and agreed to pay royalties on future products. In addition, bioMérieux 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 full term of this agreement. In November 2003, the Company had completed its research obligations under this alliance and received research payments of approximately $5.2 million through December 31, 2003 under this agreement.

The Company recognized approximately $1,173,000, $1,188,000 and $1,089,000, in revenue during the years ended December 31, 2001, 2002 and 2003, respectively, which consisted of alliance research revenue and amortization of the up-front license fee.

(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 focuses on developing therapeutics utilizing targets based on the characterization of a gene associated with a unique high bone mass trait.

The agreement provides for the Company to employ its established capabilities in positional cloning, bioinformatics and functional genomics in conjunction with Wyeth s drug discovery capabilities and its expertise in bone biology and the osteoporotic disease process to develop new pharmaceuticals. Under the terms of the

agreement, Wyeth agreed to pay an up-front license fee, milestone payments and fund a research program for three years, as well as pay royalties based upon sales of therapeutic products developed from this collaboration. In December 2003, the Company completed its research obligation under this alliance and received approximately $10.3 million through December 31, 2003 in research payments under this agreement. If substantially all of the milestone payments are met, total payments to the Company, excluding royalties, would exceed $119 million.

The Company recognized approximately $6,485,000, $1,060,000 and $1,094,000, in revenue during the years ended December 31, 2001, 2002 and 2003, respectively, which consisted of alliance research revenue, amortization of the up-front license, 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. In January 2004, both companies agreed to conclude the research collaboration effective April 7, 2004. With the conclusion of this research program, the Company will retain certain intellectual property and licensing rights related to its gene discovery. The Company received approximately $5.2 million through December 31, 2003, consisting of $4.7 million in research payments, a milestone payment and a license fee and $500,000 in an equity investment in the Company by Amgen.

The Company recognized approximately $42,000 and $4,200,000, in revenue during the years ended December 31, 2002, and 2003, respectively, which consisted of alliance research revenue, milestone payments and amortization of the up-front license fee.

GENOME THERAPEUTICS CORP. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(13) QUARTERLY CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

The following table sets forth unaudited quarterly statement of operations data for each of the eight quarters in the two year period ended December 31, 2003. 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	Year
2002					
Revenues:					
Biopharmaceutical	$ 2,433,725	$ 1,927,960	$ 1,844,312	$ 1,509,995	$ 7,715,992
Genomics services	3,730,792	4,056,708	3,155,353	4,328,010	15,270,863
Total revenues	6,164,517	5,984,668	4,999,665	5,838,005	22,986,855
Costs and Expenses:					
Cost of services	3,413,790	3,698,688	3,071,806	4,856,322	15,040,606
Research and development	7,846,081	8,286,908	9,206,536	7,126,316	32,465,841
Selling, general and administrative	2,057,385	2,188,430	2,629,129	2,506,987	9,381,931
Total costs and expenses	13,317,256	14,174,026	14,907,471	14,489,625	56,888,378
Loss from operations	(7,152,739)	(8,189,358)	(9,907,806)	(8,651,620)	(33,901,523)
Other Income (Expense):					
Interest income	530,932	494,671	400,636	342,451	1,768,690
Interest expense	(216,090)	(628,126)	(557,865)	(534,036)	(1,936,117)
Gain (loss) on sale of assets	53,121	5,326	(7,582)	1,060	51,925
Net other income (expense)	367,963	(128,129)	(164,811)	(190,525)	(115,502)
Net loss	$ (6,784,776)	$ (8,317,487)	$ (10,072,617)	$ (8,842,145)	$ (34,017,025)
Net Loss per Common Share:					
Basic and diluted	$ (0.30)	$ (0.36)	$ (0.44)	$ (0.38)	$ (1.48)
Weighted Average Common Shares Outstanding:					
Basic and diluted	22,798,224	22,812,226	23,032,463	23,040,590	22,920,875

GENOME THERAPEUTICS CORP. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	Quarter One	Quarter Two	Quarter Three	Quarter Four	Year
2003					
Revenues:					
Biopharmaceutical	$ 1,454,357	$ 1,457,057	$ 2,607,967	$ 1,489,794	$ 7,009,175
Genomics services	1,284,693	252,974	261,573	250,198	2,049,438
Total revenues	2,739,050	1,710,031	2,869,540	1,739,992	9,058,613
Costs and Expenses:					
Cost of services	1,902,561				1,902,561
Research and development	6,715,440	4,337,911	6,487,736	4,621,993	22,163,080
Restructuring charge		3,990,748	742,166	524,348	5,257,262
Convertible debt retirement expense		5,527,833	12,500		5,540,333
Selling, general and administrative	2,224,364	1,668,797	1,569,768	1,940,611	7,403,540
Total costs and expenses	10,842,365	15,525,289	8,812,170	7,086,952	42,266,776
Loss from operations	(8,103,315)	(13,815,258)	(5,942,630)	(5,346,960)	(33,208,163)
Other Income (Expense):					
Interest income	232,079	147,582	80,619	120,512	580,792
Interest expense	(710,452)	(261,872)	(23,653)	5,578	(990,399)
(Loss) Gain on sale of fixed assets	(130,001)	(2,157)	73,636	241,928	183,406
Other income				3,645,612	3,645,612
Net other income (expense)	(608,374)	(116,447)	130,602	4,013,630	3,419,411
Net loss	$ (8,711,689)	$ (13,931,705)	$ (5,812,028)	$ (1,333,330)	$ (29,788,752)
Net Loss per Common Share:					
Basic and diluted	$ (0.37)	$ (0.58)	$ (0.22)	$ (0.04)	$ (1.13)
Weighted Average Common Shares Outstanding:					
Basic and diluted	23,595,026	24,192,302	25,956,357	31,415,827	26,289,876

(14) ACCRUED EXPENSES

Accrued expenses consist of the following:

	December 31,

	2002	2003
Payroll and related expenses	$ 2,278,679	$ 1,497,295
Facilities	368,601	240,623
Professional fees	180,000	492,926
Severance		612,241
Interest related to convertible notes payable	453,699	
All other	798,169	640,223
	$ 4,079,148	$ 3,483,308

GENOME THERAPEUTICS CORP. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(15) SUBSEQUENT EVENTS

Merger with GeneSoft Pharmaceuticals, Inc. and Sale of Common Stock

On February 6, 2004, the Company completed its acquisition of Genesoft, a privately-held company incorporated in Delaware. The Company estimated that the aggregate purchase price would be approximately $100 million. As a result of the merger, the Company issued approximately 25.2 million shares of the Company s common stock to existing Genesoft common stockholders and promissory note holders and 3.4 million shares will be reserved for future issuance upon the exercise of Genesoft stock options and warrants assumed in the merger. In connection with the closing of the merger, the Company assumed approximately $22 million in Genesoft debt, through the issuance of 5% convertible promissory notes. Such notes are convertible, at the option of the holder, into shares of the Company s common stock at a price of $6.6418 per share.

Concurrent with the merger, the Company sold 16.8 million shares of its common stock at $5.25 per share resulting in proceeds received of approximately $81 million, net of issuance costs.

The Company will account for this merger under the purchase method of accounting for business combinations under the provisions of Statement of Financial Accounting Standards (SFAS) No. 141 Business Combinations during its first quarter of fiscal year 2004. The following unaudited pro forma financial information presents the combined results of the operations and financial position of Genesoft and the Company as if the merger had occurred as of January 1, 2002 and for the balance sheet data as if the merger had occurred as of December 31, 2003. The unaudited pro forma financial information also includes the net proceeds of $81 million received from the sale of the Company s common stock on February 6, 2004.

	December 31,	
	2002	2003
	(unaudited)	
(Dollars in thousands, except per share amounts)		
Net revenue	$ 28,389	$ 13,146
Net loss	(66,109)	(62,388)
Loss per common share basic and diluted	(1.01)	(.91)
Cash, cash equivalents, restricted cash and marketable securities		$ 107,183
Total assets		237,717
Total liabilities		52,374

On February 2, 2004, at a special meeting of the Company s shareholders, the shareholders approved an increase in the number of shares of common stock that the Company is authorized to issue from 50,000,000 to 175,000,000.