OSCIENT PHARMACEUTICALS CORP
Form ARS
May 06, 2005
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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, 2004

OR

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

Commission file number: 0-10824

OSCIENT PHARMACEUTICALS CORPORATION

(Exact name of registrant as specified in its charter)

Massachusetts	**04-2297484**
(State or other jurisdiction of incorporation or organization)	**(IRS employer identification number)**
1000 Winter Street Suite 2200, Waltham, Massachusetts	**02451**
(Address of principal executive offices)	**(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 x No ¨

The aggregate market value of the voting and non-voting common equity held by non-affiliates as of June 26, 2004, the last business day of the registrant s most recently completed second fiscal quarter, was approximately $329,200,000.

The number of shares outstanding of the registrant s common stock as of March 10, 2005 was 76,383,155.

Documents Incorporated By Reference. Portions of the registrant s proxy statement for use at its Annual Meeting to be held May 25, 2005 incorporated by reference into Part III.

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Oscient Pharmaceuticals Corporation

Annual Report

on Form 10-K

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PART I

This annual report on Form 10-K contains forward-looking statements that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause the results of Oscient Pharmaceuticals to differ materially from those expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including any projections of revenue, expenses, earnings or losses from operations, or other financial items; any statements of the plans, strategies and objectives of management for future operations; any statements concerning product research, development and commercialization timelines; any statements of expectation or belief; and any statements of assumptions underlying any of the foregoing. The risks, uncertainties and assumptions referred to above include risks that are described under the heading Risk Factors in Management s Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this annual report and that are otherwise described from time to time in our Securities and Exchange Commission reports filed after this report.

The forward-looking statements included in this annual report represent our estimates as of the date of this annual report. We specifically disclaim any obligation to update these forward-looking statements in the future. These forward-looking statements should not be relied upon as representing our estimates or views as of any date subsequent to the date of this annual report.

Item 1. Business

OVERVIEW

We are a biopharmaceutical company committed to the clinical development and commercialization of new therapeutics to serve unmet medical needs. We are currently a commercial-stage biopharmaceutical company focused on expanding our business in the primary care physician marketplace in the United States. In September of 2004, we launched our first product, the fluoroquinolone antibiotic FACTIVE® (gemifloxacin mesylate) tablets. Additionally, we have two product candidates for the hospital marketplace in the United States currently in development.

The Company s lead product, marketed in primary care, is the fluoroquinolone antibiotic FACTIVE (gemifloxacin mesylate) tablets, FDA-approved for the treatment of community-acquired pneumonia of mild-to-moderate severity (CAP) and acute bacterial exacerbations of chronic bronchitis (AECB). The commercial sale of FACTIVE began in September 2004. FACTIVE is also being studied in a Phase III study to explore shorter duration therapy for CAP and we are in discussions with the FDA regarding an additional indication acute bacterial sinusitis (ABS) for FACTIVE.

Our hospital product portfolio includes a novel antibiotic candidate, Ramoplanin, which is currently in clinical development for the treatment of a serious hospital-acquired infection. Ramoplanin has been studied in a Phase II trial for the treatment of *Clostridium difficile*-associated diarrhea (CDAD) and we are currently in discussions with the FDA in connection with a special protocol assessment for the design of a Phase III program for the indication. Additionally, we have an intravenous formulation of FACTIVE in development, intended for use in hospitalized patients with pneumonia.

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 pursuant to which, among other things, we acquired the rights to commercialize FACTIVE. Following that merger, we renamed the Company, from Genome Therapeutics to Oscient Pharmaceuticals, and began focusing on the development and commercialization of our own products. We retain a number of pre-clinical assets based on the prior business strategies of both Genome Therapeutics and

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Genesoft Pharmaceuticals. These include an oral peptide deformylase inhibitor series for the potential treatment of respiratory tract infections. We also have rights to potential future milestone and royalty payments under several pharmaceutical alliances focused on the development of novel therapeutics and diagnostics for chronic human diseases and certain infectious diseases.

BUSINESS STRATEGY

Our goal is to become a leading biopharmaceutical company focused on the clinical development and commercialization of new therapeutics. The key elements of our strategy to achieve this goal are as follows:

Expanded Marketing and Further Development of FACTIVE Tablets

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

Building our Primary Care Business Through New Products

We will continue to explore ways of expanding our primary care commercial offerings and product portfolio through the co-promotion, licensing or acquisition of complementary products and product candidates.

Building a Hospital Business Clinical Development of Ramoplanin and intravenous FACTIVE

Our lead product candidate is our novel antibiotic, Ramoplanin. We are advancing the clinical program of Ramoplanin toward a Phase III trial for the treatment of *Clostridium difficile*-associated diarrhea. The intravenous form of FACTIVE, for use in hospitalized patients, is also in development.

Capturing Value in Legacy Assets

We are exploring avenues for capturing value in our preclinical oral peptide deformylase inhibitor compounds, most likely through a partner. We also continue to monitor the progress of our pharmaceutical alliance partners and explore the possibility of selling intellectual property retained from the prior businesses of Genome Therapeutics and Genesoft Pharmaceuticals.

PHARMACEUTICAL PROGRAMS

We have three ongoing product programs. Our lead program is FACTIVE oral tablets, for which we are seeking to supplement our current FDA approved claims by pursuing additional indications and treatment regimens. Our portfolio also includes Ramoplanin, a

novel antibiotic in clinical development for the treatment of *Clostridium difficile*-associated diarrhea (CDAD) and the intravenous form of FACTIVE.

Our preclinical legacy assets include an oral peptide deformylase inhibitor series retained from Genesoft Pharmaceuticals and the rights to potential future milestone and royalty payments under five alliances based on the prior genomics discovery business of Genome Therapeutics (a summary of the biopharmaceutical alliances is included in the MD&A).

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.

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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, fluoroquinolones, 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 fluoroquinolone 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 fluoroquinolones 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-Acquired Respiratory Tract Infections (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 AECB, 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, fluoroquinolones 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 fluoroquinolones as a first line treatment for certain higher-risk patients with CAP.

FACTIVE Tablets

We have the marketing rights for 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 was approved by the FDA for the treatment of AECB and CAP of mild to moderate severity. In July 2003, FACTIVE was also approved by the FDA 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 was the first antimicrobial approved for this indication. In April of 2004, FACTIVE received marketing approval in Canada for the treatment of AECB.

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FACTIVE has 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 is bactericidal at clinically achievable concentrations. Gemifloxacin, the active ingredient in FACTIVE, targets two enzymes in bacteria and has minimum inhibitory concentrations, or MICs, as low as 0.03 µg/ml for *S. pneumoniae*. In clinical trials, FACTIVE was administered to 6,775 patients and had a good overall safety and tolerability profile comparable to other currently marketed antibiotics. FACTIVE has been the subject of over 200 scientific publications. Among the research published are data indicating the drug s ability to reduce the number of AECB recurrences over a six-month period following treatment.

Within the antibiotic market, fluoroquinolones, a product class with close to $3 billion in annual sales in the U.S. in 2004, have been gaining market share at the expense of older antibiotics, according to NDC Health. This is a trend that is expected to continue as resistance to older antibiotic classes increases. Due to its microbiological activity and clinical efficacy, FACTIVE represents 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. FACTIVE is 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 included 14 Phase III trials in respiratory tract infections. FACTIVE was 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 AECB studies demonstrated that FACTIVE given once daily for 5 days was 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 was also studied for the treatment of community-acquired pneumonia (CAP) 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, including 1,037 patients treated for 7 days, while 927 patients were treated with an active comparator. The primary endpoint for each of these three trials was clinical response at follow-up.

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The results of these studies showed that gemifloxacin was effective in the treatment of mild to moderate CAP. The clinical success rates for FACTIVE 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%

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

Competitive Advantages: We believe the competitive advantages of FACTIVE tablets include:

- FACTIVE has been shown in *in vitro* studies to be active against many bacterial isolates resistant to other classes of antibiotics, and was the first antibiotic approved to treat community-acquired pneumonia of mild to moderate severity caused by multi-drug resistant *S. pneumoniae.*
- FACTIVE has a dual mechanism of action in bacteria, targeting two enzymes essential for bacterial growth and survival at therapeutically relevant drug levels, and as a result we believe has low *in vitro* potential for resistance generation.
- FACTIVE can be dosed once daily, with short courses of therapy for both AECB (5 days) and CAP (7 days).
- FACTIVE has patent protection into 2019, longer than any currently marketed fluoroquinolone or other antibiotic widely used to treat respiratory tract infections.

Safety and Tolerability: FACTIVE tablets were studied in nearly 7,000 patients in clinical trials and we estimate that to date, over 100,000 patients have taken FACTIVE since launch. In clinical trials, 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. The most common adverse events reported in FACTIVE clinical trials were diarrhea, rash and nausea. In clinical trials, rash was reported in 2.8% of patients receiving gemifloxacin and was more commonly observed in patients less than 40 years of age, especially females. Since the launch of the drug, the adverse events reported have been consistent with those observed in the clinical development program, and with the fluoroquinolone class as a whole.

As a post-marketing commitment to the FDA, we are conducting a Phase IV trial of FACTIVE. This prospective, randomized study is comparing FACTIVE tablets (5,000 patients) to an active comparator (2,500 patients) in patients with CAP or AECB. This study includes patients of different ethnicities so that we can ascertain 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 was initiated in the fall of 2004 with expected completion within three to four years.

Additional Development of Gemifloxacin: Clinical trials of FACTIVE 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

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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. Three open-label studies also support the efficacy of FACTIVE tablets given for 5 days for the treatment of ABS. It is our belief that all necessary clinical trials are complete and that the gathering of additional data from the post-marketing experience of the drug will supplement our NDA filing although how long or how much data will be required is not yet determined. We are in discussions with the FDA concerning the regulatory requirements for potential submission of a New Drug Application (NDA) for this indication in 2005.

We are also developing an intravenous formulation of gemifloxacin. We expect that FACTIVE intravenous will need to undergo a Phase I bioequivalence study plus, pending a successful outcome of the first study, we believe a single Phase III trial of the intravenous formulation would be required before seeking marketing approval from the FDA.

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 the patent life of the compound which currently expires in 2018 with respect to the principal composition of matter 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 achievement of a minimum level of sales commitment over a period of time, which if not met, would result in the product 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 territories; provided, that LG Life Sciences has the right to co-promote the product, on terms to be negotiated, in our territories beginning in 2008 and periods commencing thereafter.

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 up to $22 million when specific commercialization milestones are achieved. We are required to buy bulk drug from LG Life Sciences (see Manufacturing below), and will pay LG Life Sciences a royalty on sales in North America and the territories covered by the license in Europe.

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.

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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 emergence of vancomycin-resistant organisms, including vancomycin-resistant enterococci (VRE). Resistance has also been reported for metronidazole.

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 infections caused by *C. difficile* that occur in the GI tract.

Clinical Trials: In July of 2004, we completed our Phase II trial to assess the safety and efficacy of Ramoplanin in the treatment of CDAD. The open-label study enrolled 87 people in 24 U.S. sites. The trial compared 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 were administered for ten days, during which data on Ramoplanin was collected to measure safety and efficacy. The primary endpoint of the study was response rate at the test-of-cure visit, 7-14 days post-therapy. For this trial, the response rates were 60% for Ramoplanin 200 mg, 71% for Ramoplanin 400 mg, and 78% for vancomycin 125 mg in the clinically evaluable population. A potentially more clinically relevant endpoint, response at the end of therapy, was also assessed. At the end of therapy, the response rates were 83% for Ramoplanin 200 mg, 85% for Ramoplanin 400 mg and 86% for vancomycin 125 mg. We have submitted a special protocol assessment (SPA) to the FDA for the Phase III program of Ramoplanin for CDAD. These Phase II results are being discussed with the FDA as part of our SPA submission. Pending a successful outcome of these discussions and successful timetable discussions with our partner, Vicuron, the program would be ready to initiate the Phase III trial. 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.

Previously, Ramoplanin was studied in a Phase II, multicenter, double-blind, placebo-controlled trial examining suppression of GI VRE colonization. In that study, Ramoplanin was well tolerated. After seven days of treatment, 90% of patients who were colonized with VRE at the beginning of the study had no detectable VRE in their GI tract, while all of the placebo patients had detectable VRE (p=0.01). Ramoplanin was also studied in a Phase III trial for the prevention of bloodstream infections caused by vancomycin-resistant enterococci. That studied was closed prior to completion, due to slow enrollment, and we expect to use the data from the study as part of a safety database for Ramoplanin. Additionally, we conducted a Phase I study of Ramoplanin for the potential control of VRE transmission in the hospital-setting.

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

- 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 that normally colonize the GI tract making it less likely that its use will result in the overgrowth of other opportunistic organisms.

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 active pharmaceutical ingredients 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. Pursuant to the terms of our amended agreement with Vicuron, we and Vicuron are in discussions to develop a timetable for the development of Ramoplanin to determine an outside date for the filing of an NDA.

LEGACY GENOMICS-BASED 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 existing pharmaceutical alliances still have the potential to deliver value in the future. We believe these programs (a summary of these programs is included in the MD&A) all to be in the preclinical stage of development.

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. We believe 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

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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. The next step is to focus 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.* Continued success of this program is contingent on securing a development partnership with another organization.

DISCONTINUATION OF GENOMICS SERVICES BUSINESS

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. As of December 31, 2004, we have received approximately $792,000 in royalties.

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 for approximately $181,000 from subscriber discoveries, and 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 63 issued U.S. patents, approximately 84 pending U.S. patent applications, 113 issued foreign patents and approximately 198 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;

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- 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. 6,723,734 granted April 20, 2004, relating to the salt of naphthyridine carboxylic acid derivative; licensed from LG Life Sciences, expiring March 20, 2018;
- U.S. Patent No. 6,803,376 granted October 12, 2004, relating to methods of use of quinolone compounds against pneumococcal pathogenic bacteria; licensed from LG Life Sciences; expiring September 21, 2019.

We are not currently involved in any litigation, settlement negotiations, or other legal action regarding patent issues and we are not aware of any patent litigation threatened against us. Our patent position involves complex legal and factual questions, and legal standards relating to the validity and scope of claims in the applicable technology fields are still evolving. Therefore, the degree of future protection for our proprietary rights is uncertain.

Under our license agreement with LG Life Sciences, we obtained an exclusive license to develop and market gemifloxacin in certain territories. This license covers 15 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 2018, 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.

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.

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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. Patents 944 and 468 have been reexamined with relatively minor modifications to the claims and confirmed patentable over the submitted references.

Under our agreement with Vicuron, we obtained an exclusive license to develop and market oral Ramoplanin in the United States and Canada. The patents to Ramoplanin that we licensed 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. 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.

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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;
- ketolides, such as Ketek® (telithromycin), a product of Sanofi-Aventis,
- 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, many generic antibiotics are also currently prescribed to treat these infections.

Ramoplanin is currently in development for the for the treatment of *Clostridium difficile*-associated diarrhea (CDAD). We are aware of two products currently utilized in the marketplace Vancocin® (vancomycin), a product of ViroPharma, and metronidazole, a generic product for treatment of this indication. We are also aware of at least two companies with products in development for the treatment of CDAD a Genzyme compound which has completed Phase II; and an Acambis compound in Phase I. 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 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 and product candidates is and will be based on, among other things:

- our sales and marketing expertise,
- our clinical trial results and post marketing experience,
- 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 to attract and retain qualified personnel,
- our ability to obtain patent protection and defend our patent challenges,
- our ability to in-license product candidates for clinical development,
- our ability to secure sufficient capital resources to fund our research, clinical development and sales and marketing operations, and
- our ability and our partners ability to develop and commercialize therapeutic, vaccine and diagnostic products based upon our discoveries.

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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 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 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 genomics-based 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 may also develop diagnostic products based upon the human or pathogen genes that we identified. 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 develop as a Class III device, requiring pre-market approval.

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Obtaining pre-market 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 AECB. 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 underway. The results of this trial, if unfavorable, 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.

We are selling FACTIVE through our own sales and marketing organization in the U.S. Our sales representatives, currently contracted through Publicis Selling Solutions (PSS), focus on high-prescribing primary care physicians and opinion leaders who represent about 40% of the total respiratory tract infection prescription universe. We intend to seek a co-promotion partner in the U.S. to broaden our marketing efforts. We have also built a team of professionals with experience in medical education, insurance and government reimbursement, medical affairs, marketing, advertising and scientific communications.

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.

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We also have the exclusive right to market Ramoplanin in the U.S. and Canada, if approved by regulatory authorities.

MANUFACTURING

In October 2002, Genesoft, now our subsidiary, 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 with respect to each country extends at least through the life of the patents covering gemifloxacin in such country. In the United States, the last of the currently issued patents expires in 2019. 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 the agreement, LG Life Sciences has agreed to supply and we are obligated to purchase from LG Life Sciences all of the Company s anticipated commercial requirements for FACTIVE bulk drug. LG Life Sciences is expected to supply the FACTIVE bulk drug substance from its manufacturing facility in South Korea. We have initiated a technology transfer process with Patheon Inc. for the manufacture of finished products, to replace the previous fill and finish provider, SB Pharmco. We estimate that Patheon will obtain the necessary FDA qualifications to be the fill and finish provider of FACTIVE tablets during the first half of 2005. We expect that the quantities of FACTIVE tablets currently on hand, in combination with the quantities to be delivered from SB Pharmco, pursuant to pending purchase orders, will provide us with sufficient inventory until Patheon can be qualified. Assuming success on ongoing testing on the validation batches of FACTIVE tablets prepared by Patheon, these validation batches and additional inventory of tablets at Patheon are expected to be available for commercial use during the second quarter of 2005.

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 and would also plan to use a contract manufacturer to produce the final dosage to support commercial 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, 2004, we had 94 full-time equivalent employees, with 20 of these employees engaged in clinical development, 42 of them conducting sales and marketing functions and 32 providing general and administrative capabilities. Three of our employees held M.D.s and 26 more held other advanced degrees including MBAs, Juris Doctors or equivalent degrees. In addition, we had 171 sales representatives in our contract sales force. It is expected that our sales force will change from contract status to full-time employee status sometime in 2005. This agreement affords us the flexibility to hire, train and manage a large sales force and to evaluate talent over time. We met our goal of hiring 106 sales representatives at the time of the launch of FACTIVE, and we had 171 at year-end 2004 and expect to complete the remaining sales force hiring in early 2005, bringing the total to 250.

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

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AVAILABILITY OF INFORMATION

We maintain a website with the address www.oscient.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.

Item 2. Properties

FACILITIES

Our executive offices moved during the year from 100 Beaver Street, Waltham, Massachusetts to 1000 Winter Street, Suite 2200, Waltham, Massachusetts. We lease approximately 36,000 square feet of space at our Winter Street facility and our lease expires on March 31, 2012. We lease approximately 81,000 square feet of space at the 100 Beaver Street facility, and our lease expires on November 15, 2006. During 2004, we incurred aggregate rental costs, excluding maintenance, tax and utilities, for our Waltham facilities of approximately $1,225,000. We have subleased approximately 44,000 square feet at our former Beaver Street facility as of December 31, 2004. In 2004, we received approximately $914,000 in sublease income.

Subsequent to our merger with Genesoft, we also maintain a west coast lease obligation at 7300 Shoreline Court, South San Francisco, California, for approximately 68,000 square feet of laboratory and administrative space. The average yearly base rent for the west coast facility is approximately $4,485,000. The lease for this facility expires on February 28, 2011 and we have sub-leased to third parties approximately 50,000 square feet of the facility through December 31, 2004. We received in 2004 approximately $1,638,000 in sublease income from the west coast sublease.

Item 3. Legal Proceedings

None.

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

None.

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PART II

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

Our common stock is traded on the Nasdaq National Market System (ticker symbol OSCI). The table below sets forth the range of high and low sale prices for each fiscal quarter during 2003 and 2004 as reported by the National Association of Securities Dealers Quotation System.

	2004		2003	
	High	Low	High	Low
First Quarter	$ 7.18	$ 3.05	$ 2.11	$ 1.16
Second Quarter	6.85	4.36	4.00	1.40
Third Quarter	5.29	3.25	3.49	2.28
Fourth Quarter	3.92	2.71	3.64	2.55

As of March 4, 2005, there were approximately 1,188 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.

In the second quarter of 2004 the Company sold $152.75 million aggregate principal amount of 3.5% senior convertible notes, due 2011, for proceeds, net of initial purchaser discounts, of approximately $147 million. The notes were sold in private placements exempt from registration under Section 4(2) of the Securities Act of 1933, as amended. J.P. Morgan Securities Inc. and Merrill Lynch, Pierce, Fenner & Smith Incorporated purchased $125 million principal amount of the notes on May 10, 2004 and an additional $18.75 million principal amount of the notes on May 25, 2004. Smithfield Fiduciary LLC purchased $6,000,000 principal amount of the notes on May 25, 2004 and $3,000,000 principal amount of the notes on June 4, 2005.

The notes are convertible into the Company s common stock, at the option of the holders, at an initial conversion price, subject to adjustment, of 150.5571 shares per $1,000 principal amount of notes (representing an initial conversion price of approximately $6.64 per share). Holders of the notes may require us to repurchase all or a portion of their notes, subject to specified exceptions, at a price equal to 100% of the principal amount of the notes, plus, in certain circumstances, a make-whole premium, upon a change of control of the Company or a termination of trading of the Company s common stock.

Equity Compensation Plan Information

Plan category	Number of securities to be issued upon exercise of outstanding options	Weighted-average exercise price of outstanding	Number of securities remaining available for future issuance under equity compensation plans (excluding securities

		options	reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders	7,637,170	$ 4.47	4,744,588

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Item 6. Selected Consolidated Financial Data

You should read carefully the financial statements included in this report, including the notes to the financial statements and Management s Discussion and Analysis of Financial Condition and Results of Operations. The selected financial data in this section are not intended to replace the financial statements.

We derived the statement of operations data for the years ended December 31, 2004, 2003 and 2002 and the balance sheet data as of December 31, 2004 and 2003 from our audited financial statements, which are included elsewhere in this report. We derived the statement of operations data for the years ended December 31, 2001 and 2000 and the balance sheet data as of December 31, 2002, 2001 and 2000 from our audited financial statements which are not included herein. Historical results are not necessarily indicative of future results. See the notes to the financial statements for an explanation of the method used to determine the number of shares used in computing basic and diluted net loss per common share.

	For the Year Ended December 31,				
	2004	2003	2002	2001	2000
Revenues:					
Product sales	$ 4,067,284	$	$	$	$
Biopharmaceutical	2,545,623	7,009,175	7,715,992	18,438,286	11,851,091
Total operating revenues [1]	6,612,907	7,009,175	7,715,992	18,438,286	11,851,091
Operating expenses	97,228,731	39,943,335	41,460,280	32,824,989	22,065,110
Operating loss	(90,615,824)	(32,934,160)	(33,744,288)	(14,386,703)	(10,214,019)
Income (loss) from discontinued operations	207,660	(400,977)	(157,235)	1,149,532	1,879,188
Net loss	$ (93,271,272)	$ (29,788,752)	$ (34,017,025)	$ (10,090,302)	$ (5,846,839)
Net loss per common share basic and diluted	(1.33)	(1.13)	(1.48)	(0.45)	(0.27)
Weighted average basic and diluted common shares outstanding	70,349,847	26,289,876	22,920,875	22,572,427	21,376,685

[1] Does not include revenue from discontinued operations related to our Genomics business.

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	As of December 31,				
	2004	2003	2002	2001	2000
Cash and cash equivalents, restricted cash, warrant and long and short-term marketable securities	$ 176,627,740	$ 28,665,032	$ 50,866,198	$ 67,341,249	$ 73,009,887
Working capital	156,021,426	18,896,917	36,511,427	44,156,478	51,601,069
Total assets	340,559,622	40,516,315	65,845,134	82,739,598	90,251,004
Long-term liabilities	193,396,630	291,666	15,654,292	2,060,817	3,334,354
Shareholders equity	114,399,996	29,940,104	35,416,724	66,731,938	72,687,452

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 ex expressions are intended to identify forward-looking statements. All forward-looking statements involve certain risks, estimates, assumptions, and uncertainties with respect to future revenues, cash flows, expenses and the cost of capital, among other things.

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

- risks related to the successful commercialization of FACTIVE tablets, such as (i) our inability to successfully market the product due to competition from other drugs, (ii) our inability to recruit and retain a successful sales management team and sales force, (iii) lack of acceptance of the product by physicians, patients and third party payors, (iv) inability to obtain adequate distribution in wholesalers and pharmacies, and (v) problems related to manufacture or supply;
- risks related to our clinical development programs for our lead product candidate, Ramoplanin, and our programs to expand the approved indications for FACTIVE tablets, such as negative, inconclusive or insufficient results in ongoing or future clinical trials, FDA requests for additional information or data, delays in the progress of ongoing clinical trials and safety concerns arising with respect to our products or product candidates;
- 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 or the inability of our alliance partners to obtain or enforce our intellectual property rights;
- our inability or the inability of our alliance partners to successfully develop and obtain regulatory approval of products discovered based on our previous genomics-based research; and
- our dependence on key personnel.

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We have included more detailed descriptions of these and other risks and uncertainties under the heading Risk Factors below. We encourage you to read those descriptions carefully. We caution investors not to place significant reliance on the forward-looking statements contained in this report. These statements, like all statements in this report, speak only as of the date of this report (unless another date is indicated) and we undertake no obligation to update or revise the statements.

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 completed our merger with GeneSoft Pharmaceuticals, Inc., a privately-held pharmaceutical company based in South San Francisco, California. The merger was 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 were recorded, as of the date of the merger, February 6, 2004, at their respective fair values and added to those of our Company. Reported financial condition and results of operations of our Company issued after February 6, 2004 reflect Genesoft s balances and results of operations after completion of the merger, but have not been restated retroactively to reflect the historical financial position or results of operations of Genesoft. Following February 6, 2004, the earnings of the combined company 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 have finite lives and relate to FACTIVE. These amounts will be amortized over their expected useful lives. Goodwill has also been recorded; however, pursuant to SFAS No. 141, Business Combinations and SFAS No. 142, Goodwill and Other Intangible Assets, goodwill will not be amortized but subjected to annual impairment review.

The Company s lead product is the 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. The commercial sale of FACTIVE began in September 2004. For the near term, we intend to focus our efforts on commercial sales of FACTIVE tablets for these indications as well as clinical trials for other indications of FACTIVE.

The Company completed its initial recruitment of over one-hundred sales and marketing professionals in September 2004 to launch the sale of FACTIVE tablets. Shortly after launch, the Company announced the expansion of the sales force to two-hundred fifty sales representatives, through the hiring of an additional one-hundred fifty sales and marketing professionals, to support a nationwide sales force for FACTIVE. This expansion is expected to be complete by the end of the first quarter in 2005.

In addition, we are developing a novel investigational antibiotic candidate, Ramoplanin, which is currently in clinical trials for the treatment of a serious hospital-acquired infection. On August 10, 2004, we announced preliminary results of our Phase II trial of Ramoplanin for the treatment of *Clostridium difficile*-associated diarrhea (CDAD). Pending discussions with the FDA, regarding a Special Protocol Assessment, which was submitted in late 2004 and completion of discussions on timing of the clinical development program with our partner, Vicuron, the program will be ready to commence a Phase III trial. The Phase III clinical trial of Ramoplanin for the prevention of bloodstream infections caused by vancomycin-resistant enterococci (VRE) was closed early, in July 2004, due to slow enrollment. We intend to analyze the results of the VRE trial and make a determination at a later date as to any future course of action for this indication.

In 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

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of our continued evolution into a product-focused, commercial stage 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. As of December 31, 2004, we have received a total of $792,000 from Agencourt since March 14, 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 alliance 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 expect the majority of our revenue in the future to be derived through the sale of FACTIVE tablets.

We have incurred significant operating losses since our inception. As of December 31, 2004, we had an accumulated deficit of approximately $248.8 million. We expect to incur additional operating losses in the future due to the expansion of manufacturing, distribution, marketing and sales capabilities, as well as continued research and development efforts including clinical trials.

COMMERCIALIZATION OF FACTIVE

During the second half of 2004, we built a sales and marketing force and launched FACTIVE tablets on September 9, 2004. Our ability to successfully commercialize FACTIVE tablets is subject to a number of risks, including 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 other anti-infective products. If we are unable to successfully commercialize FACTIVE tablets, our operations, financial position and liquidity would be negatively affected to a significant degree.

MAJOR RESEARCH AND DEVELOPMENT PROJECTS

Research and development expenditures totaled approximately $25,819,000, $22,314,000, and $32,047,000 for the years ended December 31, 2004, 2003, and 2002, respectively.

FACTIVE (gemifloxacin mesylate) Tablets

Expenses for ongoing clinical trials and other development activities for the FACTIVE product totaled approximately $13,567,000 in 2004. Development activity and associated expense for this product did not commence until the first quarter of 2004 following our acquisition of an exclusive license for the product.

Ramoplanin

Our ongoing clinical trials and other development activities for Ramoplanin have constituted our most significant research and development projects comprising 32%, 49% and 43% of total research and development expenditures for fiscal years 2004, 2003 and 2002, respectively. Expenses for Ramoplanin have comprised 42% of the total research and development expense since inception of the project.

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Genomics-Based Research & Alliances

Prior to the merger with Genesoft, the Company conducted genomics-based research internally and through alliance partnerships with pharmaceutical companies and government grants. The Company also maintained a genomics services business. The Company has now exited these businesses and no longer conducts research in these areas. In 2004 the expense to support these efforts was only 9% of total research and development investment. In contrast, the research and development expense to support these alliances was 23% and 16% of total research and development expenses for fiscal years ended 2003 and 2002, respectively. Research and development expense to support our alliances was 32% of the total research and development expense from January 1, 1995 through December 31, 2004. Our research phase for all our alliances ended on or before April 7, 2004.

A summary of the specific biopharmaceutical alliances that have composed our research and development program, including date initiated, alliance goal and status estimated, 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 AstraZeneca is no longer seeking clinical candidates and has returned all rights to OSCI.
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	Development of 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.
bioMerieux, 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.

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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 agreed to conclude the research collaboration effective April 7, 2004. With the conclusion of this research program, we will retain certain intellectual property and licensing rights related to the gene discovery made under this alliance.

Our ability to obtain the goal for each of these alliances is subject to numerous risks. We are heavily dependent 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 initiated a plan in 2003 to substantially reduce our research effort in internally funded early-stage target discovery programs. Under this 2003 plan, we eliminated 44 full-time positions and paid out $609,000 related to severance costs against the restructuring liability in 2004. This charge includes associated 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.

As a combined category, these research efforts represented 7%, 28% and 41% of total research and development expenses for fiscal years 2004, 2003 and 2002, respectively. These efforts comprised 42% of the total research and development expense from January 1, 1995 through December 31, 2004.

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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. Our critical accounting policies include the following:

Revenue Recognition

Principal source of revenue is the sale of FACTIVE tablets, which began shipping in the third quarter of 2004. Other sources of revenue include biopharmaceutical and genomic services. We expect our revenues derived from both our biopharmaceutical alliance and genomics services to continue to decrease in comparison to prior years and an increase in product revenues based on the launch of the sale of our FACTIVE tablets in September of 2004.

Inventory

Inventory is stated at the lower of cost or market with cost determined under the first-in, first-out (FIFO) method. As of December 31, 2004, inventory consists of FACTIVE raw material in powder form and work-in-process and FACTIVE finished tablets to be used for sample and commercial sale related to the product launch of FACTIVE in September 2004. On a quarterly basis, the Company analyzes its inventory levels, and writes down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory that is in excess of expected requirements to cost of product revenues. Expired inventory will be disposed of and the related costs will be written off. At December 31, 2004, there is approximately $4,373,000 of inventory that relates to validation lots and active pharmaceutical ingredients that are not yet saleable until the FDA acceptance of our manufacturing site at Patheon. This approval is expected in the second quarter of 2005.

Product Sales, net

We follow the provisions of Staff Accounting Bulletin No. 104 Revenue Recognition and we recognize revenue from product sales upon delivery of product to wholesalers, when persuasive evidence of an arrangement exists, the fee is fixed or determinable, title to product and associated risk of loss has passed to the wholesaler and collection of the related receivable is reasonably assured. For arrangements where risk of loss has not passed to the wholesalers or pharmacies, we defer the recognition of revenue by recording deferred revenue until such time that risk of loss has passed.

Sales Rebates, Discounts and Incentives

Our product sales are subject to various rebates, discounts and incentives that are customary in the pharmaceutical industry.

During the third quarter of 2004, we offered certain product stocking incentives to several pharmacies. These incentives included units with limited guaranteed sales provisions. As a result of these provisions, title and risk of loss of these units has not passed to the customer. Accordingly, we have deferred all revenue related to these units until such time as the unit is provided to a patient with a prescription. As of December 31, 2004, we have recorded deferred revenue of $1,302,000 related to these units.

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During the fourth quarter of 2004, we initiated a sample card program whereby we offered an incentive to patients in the form of free full-course sample card. We have accounted for this program in accordance with Emerging Issues Task Force Issue No. 01-09, *Accounting for Consideration Given by a Vendor to a Customer* (EITF 01-09). As of December 31, 2004, we did not have sufficient history with these types of incentive programs in order to develop a reasonable and reliable estimate of the amount of reimbursement claims that we expect to realize. As a result, we have recorded the maximum liability (100% redemption) for reimbursement claims related to sample cards offered as of December 31, 2004. The Company will adjust the liability upon completion of the program and may be able to consider the actual redemption rate in estimating the liability for similar programs in the future.

Our product sales are made to pharmaceutical wholesalers for further distribution through pharmacies to the ultimate consumers of our product. All revenues from product sales are recorded net of applicable allowances for returns, wholesaler chargebacks, cash discounts, and administrative fees. We estimate wholesaler chargebacks, cash discounts, administrative fees and other rebates by considering the following factors: current contract prices and terms, estimated customer and wholesaler inventory levels and current average chargeback rates. Our process to estimate product returns includes the remaining shelf life and the product life cycle stage. We estimate product return allowances based on historical information for similar or competing products in the same distribution channel. We obtain and evaluate product return data from distributors and, based on this evaluation, estimate return rates. The reserves are reviewed at each reporting period and adjusted to reflect data available at that time. To the extent the Company s estimates of contractual allowances, rebates and sales returns are different from actuals, the Company adjusts the reserve which impacts the amount of product sales revenue recognized in the period of the adjustment. The Company has not received any significant returns through December 31, 2004.

Genomics-Based Research & Alliances and Genomics Services

Genomics-Based Research and Alliances revenues have consisted of government grants, license fees and contract research and milestone payments from alliances with pharmaceutical companies. Genomics services revenues have consisted 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 reasonably assured. 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 we are 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. Milestone payments are recognized upon achievement of the milestone as long as the milestone is non-refundable, is deemed to be substantive and we have no other performance obligations related to the milestone. Unbilled costs and fees represent revenue recognized prior to billing. Deferred revenue represents amounts received prior to revenue recognition.

Clinical Trial Expense Accrual

The Company s clinical development trials related to Ramoplanin and FACTIVE are primarily conducted by third party research organizations. At the end of each accounting period, the Company estimates both the total cost and time period of the trials and the percent completed as of that

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accounting date. The Company also adjusts these estimates when final invoices are received. In July 2004, the Company decided, due to slow enrollment, to close enrollment on its Phase III clinical trial of Ramoplanin for the prevention of bloodstream infections caused by vancomycin-resistant enterococci (VRE) prior to completion of the study. The Company believes all actual and estimated costs to complete the Phase III trial are reflected in the accrual at December 31, 2004. However, readers should be cautioned that the possibility exists that the timing of the clinical trials might be longer or shorter and the cost could be more or less than we have estimated and that the associated financial adjustments would be reflected in future periods.

For the clinical development of Ramoplanin and FACTIVE, the Company recorded expenses of approximately $21,736,000, $10,829,000 and $13,868,000 for fiscal years 2004, 2003 and 2002, respectively.

Restructuring Charges

During the years ended December 31, 2004 and 2003, the Company recorded restructuring charges of $4,780,000 and $5,257,000, respectively. The Company also recorded a facility lease liability of $21,617,000 during the year ended December 31, 2004 in connection with the acquisition of Genesoft. We established exit plans for activities which took place in 2003 and 2004 and accounted for these plans in accordance with EITF Issue No. 94-3, Liability Recognition for Certain Employee Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring), Statement of Financial Accounting Standards (SFAS) No. 146, Accounting for Costs Associated with Exit or Disposal Activities and EITF Issue No. 95-3 Recognition of Liabilities in Connection with a Purchase Business Combination . In accordance with such standards, management makes certain judgemental estimates related to these restructuring charges. For example, the consolidation of facilities required us to make estimates including respect to contractual rental commitments for office and laboratory space being vacated and related costs, leasehold improvement write-downs, offset by estimated sublease income. These estimates include anticipated rates to be charged to a sub-tenant and the timing of the sublease arrangement. If the rental market changes, our sublease assumptions may not be accurate and changes in these estimates might be necessary and could materially affect our financial condition and results of operations. For example, in December 2004, we determined that the probability of subleasing our vacant space had decreased. This caused us to lower our sublease income estimate and increase our estimated liability for the fair value of the remaining lease rentals by approximately $4,730,000. If we are able to identify a sublease tenant, enter into a favorable lease buy-out or otherwise reassess our use of the vacant space, we may be required to further revise the restructuring accrual that we have recorded as of December 31, 2004. For further discussion on our restructuring activities, see Note 3 in the Notes to Consolidated Financial Statements.

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RESULTS OF OPERATIONS

Years Ended December 31, 2004 and 2003

Revenues

Total revenues decreased 6% to $6,613,000 for the year ended December 31, 2004 from $7,009,000 for the year ended December 31, 2003.

Product sales increased to $4,067,000 for the year ended December 31, 2004 from $0 for the year ended December 31, 2003 due to the commercial launch of FACTIVE tablets in September 2004. Product sales of FACTIVE tablets accounted for more than 10% of net revenues in 2004.

Biopharmaceutical revenues decreased to $2,546,000 for the year ended December 31, 2004 from $7,009,000 for the year ended December 31, 2003, primarily due to the reduction of revenues from alliances as a result of the conclusion of research agreements.

We expect our revenues derived from our biopharmaceutical alliances to continue to decrease in comparison to prior years and not have a material impact on future revenues and expect an increase in commercial product revenues as a result of our launch of FACTIVE tablets in the second half of 2004.

Costs and Expenses

Total costs and expenses increased 143% to $97,229,000 for the year ended December 31, 2004 from $39,943,000 in 2003. Cost of product sales increased to $3,380,000 in 2004 from $0 in 2003 due to the launch of FACTIVE tablets in September 2004. Included in the cost of product sales is $1,981,000 of amortization of intangible assets associated with FACTIVE.

Research and development expenses increased 16% to $25,819,000 in 2004 from $22,314,000 in 2003. Research and development activities include clinical trials, other clinical development, technology transfer and process optimization for manufacturing, and early-stage research and development funded internally as well as by government grants and strategic alliances. These research and development expenses primarily consist of salaries and related expenses for personnel, amortization of intangible assets 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. The increase in research and development is primarily due to an increase of approximately $9,985,000 in connection with the start of clinical trials for FACTIVE related to the 5-day CAP study and the FACTIVE intravenous formulation study as well as an increase of $3,582,000 in connection with the feasibility testing of FACTIVE manufacturing in a new contracted manufacturing site. Partially offsetting these increases are a decrease of approximately $2,660,000 in connection with the termination of the Ramoplanin VRE trial in July 2004, as well as decreases of $2,706,000 and $4,695,000 in cost of biopharmaceuticals revenues and internal research effort, respectively.

As part of our merger with Genesoft, we recorded a one-time non-cash charge of $11,704,000 related to in-process research and development expenses associated with internally funded early-stage target discovery programs. The valuation of the in-process research and development represents a peptide dformylase inhibitor research program (PDF) for the development of GSQ-83698 and oral PDF inhibitors, licensed from Vernalis for the treatment of community-acquired infections. In-process research and development also includes three novel metalloenzyme bacterial targets from Vernalis. Continued efforts on and success of these programs are contingent on securing a partnership with another organization. This non-cash charge was determined in the allocation for the purchase price of Genesoft.

Selling, general and administrative expenses significantly increased to $46,474,000 in 2004 from $6,298,000 in 2003. This increase was due to additional sales and marketing personnel and associated hiring and consulting costs of $16,731,000, increased other

selling and marketing costs of approximately $4,885,000 to support the launch of FACTIVE, increased advertising and promotional costs of $12,044,000, increased general and administrative personnel, hiring and

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consulting costs of approximately $5,465,000 and increased legal and patent costs of approximately $1,051,000. Selling, general and administrative expenses are expected to increase in the first half of 2005 as we continue to expand our commercialization efforts related to FACTIVE to support a national sales campaign.

Stock based compensation increased to $5,071,000 in 2004 from $534,000 in 2003. The increase is due to higher amortization of deferred compensation resulting from stock options being issued primarily at the merger, and then the expense being accelerated due to terminations of various personnel in the periods subsequent to the merger completed with Genesoft in February 2004.

Restructuring charges decreased to $4,780,000 for the year in 2004 from $5,257,000 in 2003. In 2004, we recorded restructuring charges of $4,682,000, for the impairment of the Beaver Street Waltham MA facility and associated leasehold improvements and $99,000 for severance costs. In 2003, as part of our continued effort to restructure our internally funded research programs associated with early-stage drug development, our restructuring charges included impairment charges related to the value of laboratory and computer equipment of $3,750,000 and work force reductions of another $1,507,000.

During 2003, we also recorded a non-recurring charge 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.

Other Income and Expense

Interest income significantly increased to approximately $2,424,000 in 2004 from approximately $581,000 in 2003 reflecting higher cash balances due to the proceeds of the public offering of our common stock received in the first quarter of 2004 and the convertible debt proceeds received in the second quarter of 2004 as well as higher interest rate yields from investments.

Interest expense significantly increased to approximately $5,625,000 in 2004 from approximately $990,000 in 2003, primarily due to interest expense of approximately $3,416,000 related to the issuance of $153 million of senior convertible notes in the second quarter of 2004, approximately $1,018,000 related to the issuance of $22 million of convertible notes in connection with the Genesoft merger, $521,000 related to amortization of deferred financing costs along with approximately $624,000 related to non-cash interest expense related to the facility lease liability which was recorded during the quarter ended March 27, 2004.

We recorded a gain on the sale of fixed assets of approximately $338,000 and $310,000 in 2004 and 2003, respectively, primarily related to the sale of laboratory and computer equipment, which were no longer used in operations as a result of restructuring. In 2003, other income includes a non-recurring 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.

Discontinued Operations

In 2004, we recorded income from discontinued operations of approximately $208,000 for royalty payments from Agencourt who purchased our genomics services business in March 2003. In 2003, we recorded a loss from discontinued operations of approximately $401,000. In 2003, this business generated total revenue of approximately $2,050,000 as a result of sequencing revenues and database subscriptions of approximately $1,466,000 earned prior to divestiture and royalties of

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approximately $584,000 received after divestiture. This revenue was offset by approximately $1,903,000 in cost of services and additional costs of approximately $548,000 as a result of idle equipment write-offs, loss on the sale of assets and severance costs.

Years Ended December 31, 2003 and 2002

Revenues

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

We expected our revenues derived from biopharmaceutical alliances to continue to decrease in comparison to prior years and an increase in commercial product revenues as we launched the sale of our FACTIVE tablets in September of 2004.

Costs and Expenses

Total costs and expenses decreased 4% to $39,943,000 in 2003 from $41,460,000 in 2002. 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 30% to $22,314,000 in 2003 from $32,047,000 in 2002. This decrease was primarily due to (i) the reduction in our effort in internally funded early-stage drug discovery research programs totaling $6,628,000 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 $66,000 and (iii) the reduction in expenses incurred in the clinical development of Ramoplanin of approximately $3,039,000. The reduction in clinical development expenses is primarily due to a decrease in expenditures to outside parties of $5,116,000, partially offset by higher support expenditures such as personnel, consulting and material costs of $2,077,000.

In 2003, 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 $1,508,000 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.

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Selling, general and administrative expenses decreased 31% to $6,298,000 in 2003 from $9,131,000 in 2002 driven principally by the restructuring plan, which resulted in a reduction in support staff and personnel related expenditures, consulting fees and hiring expenses.

Other Income and Expense

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

Interest expense decreased 49% to $990,000 in 2003 from $1,936,000 in 2002 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 2003, we recorded a gain on the sale of fixed assets of approximately $310,000 from the sale of certain scientific and computer equipment, which became idle as of result of our restructuring. In 2002, we recorded a gain on the sale of fixed assets of $52,000.

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.

Discontinued Operations

We recorded losses from discontinued operations of approximately $401,000 and $157,000 in 2003 and 2002 respectively. Revenue was approximately $2,050,000 and cost of services was approximately $1,903,000 in 2003 and revenue was approximately $15,271,000 and cost of services was approximately $15,041,000 in 2002. Additional expenses related to discontinued operations was approximately $548,000 in 2003 and $387,000 in 2002.

Liquidity and Capital Resources

We began generating cash from the sale of FACTIVE tablets following its launch on September 9, 2004. Our primary additional sources of cash have been payments received from proceeds from the sale of debt and equity securities, product discovery alliances, subscription fees, government grants, borrowings under equipment lending facilities and capital leases.

As of December 31, 2004, we had cash, cash equivalents and short-term marketable securities of approximately $159,652,000.

On February 6, 2004, 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 of approximately $81 million, net of issuance costs.

On February 6, 2004, in connection with our merger with Genesoft, we issued $22,309,647 in principal amount of our 5% convertible five year promissory notes. These notes are convertible into our common stock at the option of the holders, at a conversion price of $6.6418 per share (subject to anti-dilution and other adjustments). In addition, we 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. At the closing of the merger, the holders of these notes also received an aggregate 4,813,547 shares of our common stock representing the payment of accrued interest and related amounts on certain outstanding notes previously issued to them by Genesoft.

In the quarter ended June 26, 2004, we issued $152,750,000 in principal amount of our 3.5% senior convertible promissory notes due April 2011. These notes are convertible into shares of our common stock at the option of the holders at a conversion price of $6.64 per share. We may not redeem the notes at our election before May 10, 2010. After this date, we can redeem all or a part of the notes for cash at a price equal to 100% of the principal amount of the notes to be redeemed plus

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accrued and unpaid interest. Upon the occurrence of a change of control or a termination of trading of our common stock (each as defined in the indenture for the notes), holders of our notes have the right to require us to repurchase all or any portion of their notes at a price equal to 100% of the principal amount plus accrued and unpaid interest. In addition, in the case of a cash purchase of our common stock, we may have an obligation to pay an additional make-whole premium to our note holders based on a formula set forth in the indenture.

On June 4, 2003, we entered into an Amendment, Redemption and Exchange Agreement with two institutional investors providing for (a) the redemption in cash of a portion of the 6% Convertible Notes due December 31, 2004, (b) the conversion of the remaining portion of the convertible notes into our common stock and the (c) 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.

We had a loan agreement under which we have financed certain office and laboratory equipment and leasehold improvements. We had approximately $293,000 outstanding under this borrowing arrangement at December 31, 2004. This amount was fully paid off in January 2005.

Our operating activities used cash of approximately $70,381,000, $16,603,000 and $26,140,000 in 2004, 2003 and 2002, respectively. Cash used in our operating activities for 2004 was due primarily to our net operating loss of approximately $93,271,000, increase in product inventory of approximately $6,948,000 to support the launch of FACTIVE, and other increases in interest receivable, accounts receivable, prepaid expenses and other current assets as well as decreases in accrued facility impairment charge, accrued restructuring charge and the clinical trial expense accrual. These uses of cash were partially offset by increases in accounts payable, accrued expenses and other liabilities, deferred revenues, accrued other long-term liabilities, and non-cash expenses, such as amortization of deferred compensation, depreciation and amortization expense, restructuring charge, interest expense, and write-off of in-process technology. Cash used in our operating activities in 2003 was primarily due to our net loss from operations and decreases in accounts payable, clinical trial expense accrual and deferred revenues; partially offset by decreases in accounts receivable, prepaid expenses and other current assets, as well as non-cash charges, such as amortization of deferred compensation, depreciation and amortization, restructuring charge, convertible debt retirement expense, and interest expense. Cash used in our operating activities in 2002 was primarily due to our net loss from operations, an increase in accounts receivable and a decrease in deferred revenue; partially offset by decreases in interest receivable, prepaid expenses and other current assets, as well as increases in accounts payable and accrued liabilities and clinical trial expense accrual.

Our investing activities used cash of approximately $120,236,000 in 2004, and provided cash of approximately $25,302,000 and $126,000 in 2003 and 2002 respectively. Cash used by our investing activities in 2004 were primarily related to cash used at merger of approximately $14,875,000, purchases of marketable securities of approximately $143,037,000, increases in restricted cash of approximately $13,279,000 and other assets of approximately $4,238,000 as well

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as purchases of property and equipment of approximately $1,532,000. These uses of cash were partially offset by proceeds from maturities of marketable securities of approximately $55,824,000 and sale of property and equipment of approximately $892,000. Cash provided by our investing activities in 2003 and 2002 was primarily due to proceeds from maturities of marketable securities, proceeds from sale of property and equipment and increase in other assets. 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. Additionally, in 2003 the Company issued a $6.2 million bridge loan to Genesoft in connection with the merger of the two companies in Feb 2004.

Capital expenditures totaled approximately $1,532,000 in 2004, which primarily consisted of purchases of computer and related equipment to support the expanding sales force and, to a lesser degree, office furniture and leasehold improvements for the new office facilities.

Our financing activities provided cash of approximately $234,391,000 in 2004, primarily due to gross proceeds from the issuance of convertible notes of $152,750,000, net proceeds from issuance of stock through private placement in conjunction to the merger of approximately $80,864,000, proceeds from exercise of 2,129,865 stock options of approximately $1,865,000 and proceeds from exercise of warrants of approximately $195,000 and proceeds from the issuance of 125,542 shares of stock under the employee stock purchase plan of approximately $303,000. These proceeds were partially offset by payments of long-term obligations of approximately $1,586,000. Our financing activities provided cash of approximately $1,142,000 in 2003 primarily from the net proceeds from the private placement of common stock of $12,650,000, proceeds from issuance of stock from exercise of stock options and under employee purchase plan of approximately $952,000 as well as the proceeds received from a legal claim with an investor of approximately $585,000. These sources of cash in 2003 were partially offset by cash payment of $10,000,000 in connection with the redemption of the $15 million convertible notes, as well as payments on long-term obligations of approximately $3,045,000. Our financing activities provided cash of approximately $14,337,000 in 2002 primarily from the sale of convertible notes of $15 million in gross proceeds, the additional credit line for $3.5 million, of which $500,000 was used to refinance a portion of an existing line of credit, as well as from proceeds received from issuances of stock from exercise of stock options and under the employee stock purchase plan of approximately $466,000. These proceeds from financing activities were partially offset by payments of long-term obligations of approximately $4,629,000.

At December 31, 2004, we had net operating loss carryforwards of approximately $289,440,000 and $225,053,000 available to reduce federal and state taxable income respectively, if any. In addition, we also had tax credit carryforwards of approximately $18,991,000 to reduce federal and state income tax, if any. Net operating loss carryforwards are subject to review and possible adjustment by the Internal Revenue Service and may be limited in the event of certain cumulative changes in ownership interests of significant shareholders over a three-year period in excess of 50%. Additionally, certain of our losses have begun to expire due to 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 as of December 31, 2004 are adequate for at least the next two years 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 have experienced and expect to continue 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 growth, particularly in the sales and marketing areas, to continue into the first quarter of 2005 and we are in the process of hiring additional personnel to reach a total of 250 sales professionals to support nationwide sales coverage for FACTIVE.

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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):

	2005	2006	2007	2008	2009	Thereafter	Total
Operating leases	$ 5,840	$ 5,918	$ 5,098	$ 5,424	$ 5,613	$ 7,829	$ 35,722
Sublease contracted income	(3,719)	(3,719)	(1,135)				(8,573)
Current sublease forecasts [(a)]				(1,579)	(1,575)	(1,899)	(5,053)
	2,121	2,199	3,963	3,845	4,038	5,930	22,096
Term loan	293						293
Convertible promissory notes [(b)]	5,346	5,346	5,346	5,346	33,904	160,769	216,057
Total forecasted contractual obligations	$ 7,760	$ 7,545	$ 9,309	$ 9,191	$ 37,942	$ 166,699	$ 238,446

(a) The current market reflects lower demand and cost for space, as well as shorter term leases.

(b) Upon the closing of the Genesoft 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% compounded semi-annually 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 $28.6 million at maturity date includes $6.2 million of accrued interest payable

In the quarter ended June 26, 2004, the Company issued $152,750,000 in principal amount of our 3.5% senior convertible promissory notes due April 2011. These notes are convertible into our common stock at the option of the holders at a conversion price of $6.64 per share. The Company may not redeem the notes at its election before May 10, 2010. After this date, the Company can redeem all or a part of the notes for cash at a price equal to 100% of the principal amount of the notes to be redeemed plus accrued and unpaid interest. Upon the occurrence of a change of control or a termination of trading of our common stock (each as defined in the indenture for the notes), holders of our notes have the right to require us to repurchase all or any portion of their notes at a price equal to 100% of the principal amount plus accrued and unpaid interest.

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RISK FACTORS

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, the following:

Risks Related to Our Business

We have a history of significant operating losses and expect these losses to continue in the future.

We have experienced significant operating losses each year since our inception and expect these losses to continue for the foreseeable future. We had a net loss of approximately $93,271,000 for the fiscal year ended December 31, 2004 and as of December 31, 2004, we had an accumulated deficit of approximately $248,835,000. We had a net loss of approximately $29,789,000 for the fiscal year ended December 31, 2003, and, as of December 31, 2003, we had an accumulated deficit of approximately $155,564,000. For the fiscal year ended December 31, 2002, we had a net loss of approximately $34,017,000, and for the fiscal year ended December 31, 2001, we had a net loss of approximately $10,090,000. The losses have resulted primarily from costs incurred in research and development, including our clinical trials, and from general and administrative costs associated with our operations, prior to 2004, and product sales of FACTIVE tablets. These costs have exceeded our revenues which to date have been generated principally from collaborations, government grants and sequencing services.

We anticipate that we will incur additional losses in the current year and in future years and cannot predict when, if ever, we will achieve profitability. These losses are expected to continue and potentially increase as we continue significant levels of expenditures, principally in the sales and marketing area as we seek to grow sales of FACTIVE tablets and in research and development in connection with clinical trials and formulation activities to support the existing labeling of FACTIVE tablets and potentially the expanded FACTIVE labeling claims. In addition, our partners product development efforts which utilize our genomic discoveries are at an early stage and, accordingly, we do not expect our losses to be substantially mitigated by revenues from milestone payments or royalties under those agreements for a number of years, if ever.

Our business will be very dependent on the commercial success of FACTIVE tablets.

FACTIVE tablets are currently our only commercial product and we expect will likely account for substantially all of our product revenues for at least the next several years. FACTIVE tablets have FDA marketing approval for the treatment of community-acquired pneumonia of mild to moderate severity, or CAP, and acute bacterial exacerbations of chronic bronchitis, or AECB. The commercial success of FACTIVE tablets will depend upon their continued acceptance by regulators, physicians, patients and other key decision-makers as a safe, therapeutic and cost-effective alternative to other anti-infectives and other products used, or currently being developed, to treat CAP and AECB. If FACTIVE tablets are not commercially successful, we will have to find additional sources of funding or curtail or cease operations.

In December 2000, the FDA issued a non-approvable letter to the prior owner of rights to FACTIVE due, in part, to safety concerns arising out of an increased rate of rash relative to comparator drugs, especially in young women. While the FDA did approve FACTIVE tablets for marketing in April 2003, it required, as a postmarketing study commitment, that we conduct a prospective, randomized study comparing the FACTIVE tablet (5,000 patients) to an active comparator (2,500 patients) in patients with CAP or AECB. 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, with the approval from the FDA, was initiated in the second half of 2004. In connection with the approval of FACTIVE

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tablets, the FDA has also required us to obtain data on the prescribing patterns and use of FACTIVE tablets for the first three years after their initial marketing in the U.S. As part of this requirement, we will furnish periodic reports to the FDA on the number of prescriptions issued, including refills, and the diagnoses for which the prescriptions are dispensed. The results of the Phase IV trial and the periodic reports we are required to provide to the FDA, as well as other safety information arising out of the marketing of the product, could restrict our ability to commercialize FACTIVE tablets.

We may need to raise additional funds in the future.

We believe our existing funds and anticipated cash flows from operations would be sufficient to support our current plans for at least 18 months. We may need to raise additional capital in the future to fund our operations, in particular, to support our sales and marketing activities, fund clinical trials and other research and development activities, and other potential commercial or development opportunities We may seek funding through additional public or private equity offerings, debt financings or agreements with customers. Our ability to raise additional capital, however, will be heavily influenced by, among other factors, the investment market for biopharmaceutical companies and the progress of the FACTIVE and Ramoplanin commercial and clinical development programs over that period. Additional financing may not be available to us when needed, or, if available, may not be available on favorable terms. If we cannot obtain adequate financing on acceptable terms when such financing is required, our business will be adversely affected.

Future fund raising could dilute the ownership interests of our stockholders.

In order to raise additional funds, we may issue equity or convertible debt securities in the future. Depending upon the market price of our shares at the time of any transaction, we may be required to sell a significant percentage of the outstanding shares of our common stock in order to fund our operating plans, potentially requiring a stockholder vote. In addition, we may have to sell securities at a discount to the prevailing market price, resulting in further dilution to our stockholders.

We will need to develop marketing and sales capabilities to successfully commercialize FACTIVE tablets and our other product candidates.

FACTIVE tablets are our first FDA approved product. To date, we still have limited marketing and sales experience considering the launch of FACTIVE occurred September of 2004. The continued development of these marketing and sales capabilities will require significant expenditures, management resources and time. Failure to successfully establish sufficient sales and marketing capability in a timely and regulatory compliant manner or to find suitable sales and marketing partners may adversely affect our business and results of operations.

We will depend on third parties to manufacture and distribute our product and product candidates, including FACTIVE tablets and Ramoplanin.

We do not have the internal capability to manufacture pharmaceutical products under the FDA s current Good Manufacturing Practices. Under our agreement with LG Life Sciences they manufacture bulk quantities of the active pharmaceutical ingredient of FACTIVE. Although the LG Life Sciences facilities have previously been inspected by the FDA, future inspections may find deficiencies in the facilities or processes that may delay or prevent the manufacture or sale of FACTIVE tablets.

We are seeking to qualify Patheon, Inc. as a manufacturer to provide finished FACTIVE tablets, replacing SB Pharmaco. We estimate that Patheon will obtain the necessary FDA qualifications to be the fill and finish provider during the first half of 2005. The Company expects that the quantities of FACTIVE tablets currently on hand, in combination with the quantities to be delivered from SB

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Pharmco (under their current obligations), will provide sufficient inventory until Patheon can be qualified. However, if there is significant delay in the qualification of Patheon, we could have insufficient inventory of FACTIVE tablets to meet demand which could adversely affect our business and results of operations. In addition, we cannot assure you that SB Pharmco will be able to avoid batch failures or production delays for their outstanding commitments.

We cannot be certain that LG Life Sciences, Patheon, Vicuron or future manufacturers will be able to deliver commercial quantities of product candidates to us or that such deliveries will be made on a timely basis. The only source of supply for FACTIVE bulk drug product is LG Life Sciences facility in South Korea, and upon FDA qualification, Patheon will be our only source of finished FACTIVE tablets. If these facilities are damaged or otherwise unavailable, we would incur substantial costs and delay in the commercialization of FACTIVE tablets. If we are forced to find an alternative source for Ramoplanin or other product candidates, we could also incur substantial costs and delays in the further commercialization of such products. We may not be able to enter into alternative supply arrangements at commercially acceptable rates, if at all. Also, if we change the source or location of supply or modify the manufacturing process, regulatory authorities will require us to demonstrate that the product produced by the new source or from the modified process is equivalent to the product used in any clinical trials that we had conducted.

Moreover, while we may choose to manufacture products in the future, we have no experience in the manufacture of pharmaceutical products for clinical trials or commercial purposes. If we decide to manufacture products, it would be subject to the regulatory requirements described above. In addition, we would require substantial additional capital and would be subject to delays or difficulties encountered in manufacturing pharmaceutical products. No matter who manufactures the products, we will be subject to continuing obligations regarding the submission of safety reports and other post-market information.

We will depend on third parties to manage our product supply chain for FACTIVE tablets.

We do not have the internal capability to perform product supply chain services including warehousing, inventory management and distribution of commercial and sample quantities of FACTIVE tablets. In June, we entered into an exclusive agreement with Integrated Commercial Solutions, Inc. (ICS), to perform such supply chain manufacturing services for a three-year period.

We cannot be certain that ICS will be able to perform uninterrupted supply chain services throughout the term of the agreement. As our exclusive supply chain service provider if ICS were unable to perform their services for any period, we may incur substantial loss of sales to wholesalers and other purchasers of FACTIVE tablets. If we are forced to find an alternative supply chain service provider, in addition to loss of sales, we may also incur costs in establishing a new arrangement.

We cannot expand the indications for which we will market FACTIVE unless we receive FDA approval for each additional indication. Failure to expand these indications will limit the size of the commercial market for FACTIVE.

In April 2003, FACTIVE tablets were approved by the FDA for the treatment of community-acquired pneumonia of mild to moderate severity and acute bacterial exacerbations of chronic bronchitis. One of our objectives of ours is to expand the indications for which FACTIVE is approved for marketing by the FDA, including for the indication of acute bacterial sinusitis. While we believe the necessary clinical trials for acute bacterial sinusitis have been completed, we are gathering additional data based on the use of FACTIVE following commercial launch to supplement an NDA filing for acute bacterial sinusitis (ABS). We cannot be certain how much additional data will be required or whether we will be required to conduct additional clinical trials in order to market FACTIVE for this indication. In order to market FACTIVE for other indications, we will need to conduct additional clinical trials, obtain positive results from those trials and obtain FDA approval for such proposed indications. If we are

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unsuccessful in expanding the approved indications for the use of FACTIVE, the size of the commercial market for FACTIVE will be limited.

Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing FACTIVE abroad.

In order to market FACTIVE in the European Union and other foreign jurisdictions for which we have rights to market the product, we or our distribution partners must obtain separate regulatory approvals. Obtaining foreign approvals may require additional trials and expense. We may not be able to obtain approval or may be delayed in obtaining approval from any or all of the jurisdictions in which we seek approval to market FACTIVE.

Sales of FACTIVE in European countries in which we do not have rights to market the product could adversely affect sales in the European countries in which we have exclusive rights to market the product.

Our exclusive rights to market FACTIVE in Europe are limited to 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. These countries include the current members of the European Union. However, in the future, a number of additional European countries in which we do not have rights to market FACTIVE may be admitted as members of the European Union. If LG Life Sciences were to sell FACTIVE or license a third party to sell FACTIVE in such countries after they are admitted to the European Union, our ability to maintain our projected profit margins based on sales in the territories covered by the LG Life Sciences license agreement may be adversely affected because customers in our territory may purchase FACTIVE from neighboring countries in the European Union and our ability to prohibit such purchases may be limited under European Union antitrust restrictions.

Failure to secure distribution partners in foreign jurisdictions will prevent us from marketing FACTIVE abroad.

We intend to market FACTIVE through distribution partners in most, if not all, of the international markets for which we have a license to market the product. This will include the European Union, Canada and Mexico. We may not be able to secure distribution partners at all, or those that we do secure may not be successful in marketing and distributing FACTIVE. If we are not able to secure distribution partners or those partners are unsuccessful in their efforts, it would significantly limit the revenues that we expect to obtain from the sales of FACTIVE.

The development and commercialization of our products may be terminated or delayed, and the costs of development and commercialization may increase, if third parties who we rely on to manufacture and support the development and commercialization of our products do not fulfill their obligations.

Our development and commercialization strategy entails entering into arrangements with corporate and academic collaborators, contract research organizations, distributors, third-party manufacturers, licensors, licensees and others to conduct development work, manage our clinical trials, manufacture our products and market and sell our products outside of the United States. We will not have the expertise or the resources to conduct such activities on our own and, as a result, we will be particularly dependent on third parties in these areas.

We may not be able to maintain our existing arrangements with respect to the commercialization of FACTIVE or establish and maintain arrangements to develop and commercialize Ramoplanin or any additional product candidates or products we may acquire on terms that are acceptable to us. Any current or future arrangements for development and commercialization may not be successful. If we are not able to establish or maintain agreements relating to FACTIVE, Ramoplanin or any additional products we may acquire on terms which we deem favorable, our results of operations would be materially adversely affected.

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Third parties may not perform their obligations as expected. The amount and timing of resources that third parties devote to developing, manufacturing and commercializing our products are not within our control. Furthermore, our interests may differ from those of third parties that manufacture or commercialize our products. Disagreements that may arise with these third parties could delay or lead to the termination of the development or commercialization of our product candidates, or result in litigation or arbitration, which would be time consuming and expensive.

If any third party that manufactures or supports the development or commercialization of our products breaches or terminates its agreement with us, or fails to conduct its activities in a timely and regulatory compliant manner, such breach, termination or failure could:

- delay or otherwise adversely impact the development or commercialization of FACTIVE tablets, Ramoplanin, our other product candidates or any additional product candidates that we may acquire or develop;
- require us to undertake unforeseen additional responsibilities or devote unforeseen additional resources to the development or commercialization of our products; or
- result in the termination of the development or commercialization of our products.

Clinical trials are costly, time consuming and unpredictable, and we have limited experience conducting and managing necessary preclinical and clinical trials for our product candidates.

Our lead product, FACTIVE tablets, is currently conducting a Phase IV post-approval clinical trial in compliance with FDA requirements pursuant to the product s approval and a Phase III clinical trial for a five-day course of therapy for the treatment of community-acquired pneumonia of mild to moderate severity. Additionally, clinical trials may be necessary to gain approval to market the product for the treatment of acute bacterial sinusitis. Additional clinical trials will be required to gain approval to market FACTIVE for other indications/formulations.

The Phase II trial for our lead product candidate, Ramoplanin, to assess the safety and efficacy to treat *Clostridium difficile*-associated diarrhea, or CDAD, was completed in 2004. Pending completion of discussions with the FDA regarding a Special Protocol Assessment submitted in late 2004 and completion of discussions with our partner, Vicuron, concerning timelines required to complete the Phase III program and submission to the FDA, the Phase III program will be ready for initiation. Prior clinical and preclinical trials for Ramoplanin were conducted by Biosearch Italia S.p.A. and its licensees, from whom we acquired our license to develop Ramoplanin. We may not be able to complete these trials or make the filings within the timeframes we currently expect. If we are delayed in completing the trials or making the filings, our business may be adversely affected, including as a result of increased costs.

We may not be able to demonstrate the safety and efficacy of FACTIVE in indications other than those for which it has already been approved or of our other products including Ramoplanin, in each case, to the satisfaction of the FDA, or other regulatory authorities. We may also be required to demonstrate that our proposed products represent an improved form of treatment over existing therapies and we may be unable to do so without conducting further clinical studies. Negative, inconclusive or inconsistent clinical trial results could prevent regulatory approval, increase the cost and timing of regulatory approval or require additional studies or a filing for a narrower indication.

The speed with which we are able to complete our clinical trials and our applications for marketing approval will depend on several factors, including the following:

- the rate of patient enrollment, which is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study and the nature of the protocol;
- fluctuations in the infection rates for patients enrolled in our trials;
- compliance of patients and investigators with the protocol and applicable regulations;

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- prior regulatory agency review and approval of our applications and procedures;
- analysis of data obtained from preclinical and clinical activities which are susceptible to varying interpretations, which interpretations could delay, limit or prevent regulatory approval;
- changes in the policies of regulatory authorities for drug approval during the period of product development; and
- the availability of skilled and experienced staff to conduct and monitor clinical studies, to accurately collect data and to prepare the appropriate regulatory applications.

In addition, the cost of human clinical trials varies dramatically based on a number of factors, including the order and timing of clinical indications pursued, the extent of development and financial support from alliance partners, the number of patients required for enrollment, the difficulty of obtaining clinical supplies of the product candidate, and the difficulty in obtaining sufficient patient populations and clinicians.

We have limited experience in conducting and managing the preclinical and clinical trials necessary to obtain regulatory marketing approvals. We may not be able to obtain the approvals necessary to conduct clinical studies. Also, the results of our clinical trials may not be consistent with the results obtained in preclinical studies or the results obtained in later phases of clinical trials may not be consistent with those obtained in earlier phases. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after experiencing promising results in early animal and human testing.

If regulatory approval of a drug is granted, such approval is likely to limit the indicated uses for which it may be marketed. Furthermore, even if a product gains regulatory approval, the product and the manufacturer of the product will be subject to continuing regulatory review, including the requirement to conduct post-approval clinical studies. We may be restricted or prohibited from marketing or manufacturing a product, even after obtaining product approval, if previously unknown problems with the product or its manufacture are subsequently discovered.

Our product candidates will face significant competition in the marketplace.

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;
- macrolides such as Biaxin® (clarithromycin), a product of Abbott Laboratories and Zithromax® (azithromycin), a product of Pfizer Inc.; and
- Ketek, a ketolide from Aventis Pharmaceuticals; and
- penicillins such as Augmentin® (amoxicillin/clavulanate potassium), a product of GlaxoSmithKline.

Many generic antibiotics are also currently prescribed to treat these infections. Moreover, a number of the antibiotic products that are competitors of FACTIVE tablets will be going off patent at dates ranging from 2003 to 2015. As these competitors lose patent protection, makers of generic drugs will likely begin to produce some of these competing products and this could result in pressure on the price at which we are able to sell FACTIVE tablets and reduce our profit margins.

Ramoplanin is in clinical development for the treatment of *Clostridium difficile*-associated diarrhea (CDAD). We are aware of two products currently utilized in the marketplace Vancocin® (vancomycin), a product marketed by ViroPharma, 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 Geltex/Genzyme in Phase II; ImmuCell in Phase I/II; and Acambis in Phase I/II. It is also possible that other companies are developing competitive products for

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this indication. We are aware that Vicuron and Novartis Pharma are jointly developing PDF inhibitor agents that may compete with any PDF products developed by us.

All of our other internal product programs are in earlier stages and have not yet reached clinical development 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.

Many of our competitors will have substantially greater capital resources, facilities and human resources than us. Furthermore, many of those competitors are more experienced than us in drug discovery, development and commercialization, and in obtaining regulatory approvals. As a result, those competitors may discover, develop and commercialize pharmaceutical products or services before us. In addition, our competitors may discover, develop and commercialize products or services that are more effective than, or otherwise render non-competitive or obsolete, the products or services that we or our collaborators are seeking to develop and commercialize. Moreover, these competitors may obtain patent protection or other intellectual property rights that would limit our rights or the ability of our collaborators to develop or commercialize pharmaceutical products or services.

We will rely upon alliance partners from our previous Genomics-Based Research & Alliance Business as a means of developing and commercializing our products.

Our strategy for developing and commercializing therapeutic, vaccine and diagnostic products from our previous Genomics-Based Research and Alliance Business depends, in part, on strategic alliances and licensing arrangements with pharmaceutical and biotechnology partners. We currently have alliances with bioMerieux, Schering-Plough and Wyeth. Over the past several years, we have received a substantial portion of our revenue from these alliances. However, our research obligations under our strategic alliances have been fulfilled. As a result, any substantial additional revenues under these alliances will consist of milestone payments based on the achievement by the alliance partner of development milestones or royalties based on the sale of products arising from the alliance. The achievement of any of the development milestones and successful development of any products under these alliances are dependent on the alliance partners activities and are beyond our control. We cannot assure you that any milestones will be attained, that any products will be successfully developed by the alliance partners or that we will receive any substantial additional revenues under these alliances.

If our partners develop products using our discoveries, we will rely on these partners for product development, regulatory approval, manufacturing and marketing of those products before we can receive some of the milestone payments, royalties and other payments to which we may be entitled under the terms of some of its alliance agreements. Our agreements with our partners typically allow the partners significant discretion in electing whether to pursue any of these activities. We will not be able to control the amount and timing of resources our partners may devote to our programs or potential products. As a result, there can be no assurance that our partners will perform their obligations as expected.

Our failure to acquire and develop additional product candidates or approved products will impair our ability to grow.

As part of our growth strategy, we intend to acquire and develop additional product candidates or approved products. The success of this strategy depends upon our ability to identify, select and acquire biopharmaceutical products that meet our criteria. We may not be able to acquire the rights to additional product candidates and approved products on terms that we find acceptable, or at all.

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New product candidates acquired or in-licensed by us may require additional research and development efforts prior to commercial sale, including extensive preclinical and/or clinical testing and approval by the FDA and corresponding foreign regulatory authorities. All product candidates are prone to the risks of failure inherent in pharmaceutical product development, including the possibility that the product candidate will not be safe, non-toxic and effective or approved by regulatory authorities. In addition, it is uncertain whether any approved products that we develop or acquire will be:

- manufactured or produced economically;
- successfully commercialized; or
- widely accepted in the marketplace.

We will depend on key personnel in a highly competitive market for skilled personnel.

We will be highly dependent on the principal members of our senior management and key scientific and technical personnel. The loss of any of our personnel could have a material adverse effect on our ability to achieve our goals. We currently maintain employment agreements with the following senior officers: Steven M. Rauscher, President and Chief Executive Officer; Stephen Cohen, Senior Vice President and Chief Financial Officer; and Gary Patou, M.D., Executive Vice President, Chief Medical Officer, Nick Colangelo, Esq., Senior Vice President, Corporate Development and Operations, and Ton Bunt, M.D., Ph.D., Senior Vice President, Clinical Development and Medical Affairs. The term of each employment agreement continues until it is terminated by the officer or us, except for Dr. Patou s agreement which runs through March 31, 2005, after which he becomes a consultant for one year. We do not currently maintain key person life insurance on any of our employees.

Our future success is dependent upon our ability to attract and retain additional qualified sales and marketing, clinical development, scientific and managerial personnel. The plan to launch the commercial sale of FACTIVE tablets during the second half of 2004 has required us to significantly increase our hiring of new employees, primarily with expertise in the areas of sales and marketing. We will continue to increase these efforts in the future. Like others in our industry, we may face, and in the past we have faced from time to time, difficulties in attracting and retaining certain employees with the requisite expertise and qualifications. We believe that our historical recruiting periods and employee turnover rates are similar to those of others in our industry; however, we cannot be certain that we will not encounter greater difficulties in the future.

Our intellectual property protection and other protections may be inadequate to protect our products.

Our success will depend, in part, on our ability to obtain commercially valuable patent claims and protect our intellectual property. We currently own or license approximately 63 issued U.S. patents, approximately 84 pending U.S. patent applications, 113 issued foreign patents and approximately 198 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, (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;

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- 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. 6,723,734 granted April 20, 2004, relating to the salt of naphythyridine carboxylic acid derivative; licensed from LG Life Science; expiring March 20, 2018.
- U.S. Patent No. 6,803,376 granted October 12, 2004, relating to methods of use of quinolone compounds against pneumococcal pathogenic bacteria; licensed from LG Life Science; expiring September 21, 2019.

We are not currently involved in any litigation, settlement negotiations, or other legal action regarding patent issues and we are not aware of any patent litigation threatened against us. Our patent position involves complex legal and factual questions, and legal standards relating to the validity and scope of claims in the applicable technology fields are still evolving. Therefore, the degree of future protection for our proprietary rights is uncertain.

Under our license agreement with LG Life Sciences, we obtained an exclusive license to develop and market gemifloxacin in certain territories. This license covers 15 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, 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 2018, in the case of the principal patents relating to FACTIVE, 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, 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 944 and 468 have been reexamined with relatively minor modifications to the claims and confirmed patentable over the submitted references.

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.

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The risks and uncertainties that we will face with respect to our patents and other proprietary rights include the following:

- the pending patent applications that we have filed or to which they have exclusive rights may not result in issued patents or may take longer than expected to result in issued patents;
- the claims of any patents which are issued may be limited from those in the patent applications and may not provide meaningful protection;
- we may not be able to develop additional proprietary technologies that are patentable;
- the patents licensed or issued to us or our partners may not provide a competitive advantage;
- other companies may challenge patents licensed or issued to us or our partners;
- patents issued to other companies may harm our ability to do business; and
- other companies may independently develop similar or alternative technologies or duplicate our technologies; and other companies may design around technologies we have licensed or developed.

We will bear substantial responsibilities under our license agreements for FACTIVE and Ramoplanin, and there can be no assurance that we will successfully fulfill our responsibilities.

In connection with the merger, we have assumed Genesoft s exclusive license from LG Life Sciences to develop and market FACTIVE in North America and 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. Under this agreement, we are responsible, at our expense and through consultation with LG Life Sciences, for the clinical and commercial development of FACTIVE 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 FACTIVE 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 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. We believe that we are currently in compliance with our obligations under the agreement with LG Life Sciences, but there can be no assurance that we will be able to remain in compliance due to the limitations on our resources and the many risks of conducting clinical trials, as described above in Clinical trials are costly, time consuming and unpredictable, and we have limited experience conducting and managing necessary preclinical and clinical trials for our product candidates and the challenges inherent in the commercialization of new products as described above in Our product candidates will face significant competition in the marketplace.

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. The costs of pursuing any such action could substantially diminish our resources.

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Under our agreement with Vicuron, we have obtained an exclusive license to develop and market oral Ramoplanin in the United States 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. We are obligated under the agreement to work diligently to develop Ramoplanin and if we do not file an NDA for Ramoplanin by a date to be agreed upon by us and Vicuron, Vicuron would have the right to terminate our license to Ramoplanin. On November 8, 2004, we received a letter from Vicuron Pharmaceuticals Inc. indicating that they intend to seek to terminate the License and Supply Agreement between Vicuron and Oscient and reacquire rights to Ramoplanin. In their letter, Vicuron claims that it will have a right to terminate the agreement based on the fact that an NDA with respect to Ramoplanin is not expected to be filed with the FDA prior to the date originally specified in the agreement. We believe their letter contradicts an amendment to the agreement entered into in October of 2002 (filed as exhibit 10.64 to our Annual Report on Form 10-K filed with the SEC on March 31, 2003), and we have addressed this issue with Vicuron. Pursuant to the terms of the amended agreement, we are in discussions with Vicuron to develop a timetable for the completion of development and outside date for the NDA submission. There is no assurance we will be able to agree upon such a date, that Vicuron will not renew its attempt to terminate the agreement again in the future or that we will prevail in any potential dispute with Vicuron.

Vicuron is responsible for providing us with all information in its possession relating to Ramoplanin in our licensed field, for cooperating with us in obtaining regulatory approvals of Ramoplanin and for using diligent efforts to provide us with bulk Ramoplanin sufficient to carry out our clinical development activities. We believe that we are currently in compliance with our obligations under the License and Supply Agreement, but there can be no assurance that we will be able to remain in compliance due to the limitations on our resources and the many risks of conducting clinical trials, as described above in Clinical trials are costly, time consuming and unpredictable, and we have limited experience conducting and managing necessary preclinical and clinical trials for our product candidates.

Under our agreement with Vicuron, Vicuron has the obligation 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, which could be substantial; 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, including any settlement reached with Vicuron s consent, 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. The costs of pursuing any such action could substantially diminish our resources.

Our proprietary position may depend on our ability to protect trade secrets.

We rely upon trademarks, unpatented trade secrets and improvements, unpatented know-how and continuing technological innovation to develop and maintain our competitive position. We generally

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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.

We may infringe the intellectual property rights of third parties and may become involved in expensive intellectual property litigation.

The intellectual property rights of biotechnology companies, including us, are generally uncertain and involve complex legal, scientific and factual questions. Our success in developing and commercializing biopharmaceutical products may depend, in part, on our ability to operate without infringing on the intellectual property rights of others and to prevent others from infringing on our intellectual property rights.

There has been substantial litigation regarding patents and other intellectual property rights in the biopharmaceutical industry. We may become party to patent litigation or proceedings at the U.S. Patent and Trademark Office or a foreign patent office to determine our patent rights with respect to third parties which may include competitors in the biopharmaceutical industry. Interference proceedings in the U.S. Patent and Trademark Office or opposition proceedings in a foreign patent office may be necessary to establish which party was the first to discover such intellectual property. We may become involved in patent litigation against third parties to enforce our patent rights, to invalidate patents held by such third parties, or to defend against such claims. The cost to us of any patent litigation or similar proceeding could be substantial, and it may absorb significant management time. We do not expect to maintain separate insurance to cover intellectual property infringement. Our general liability insurance policy does not cover our infringement of the intellectual property rights of others. If infringement litigation against us is resolved unfavorably, we may be enjoined from manufacturing or selling certain of our products or services without a license from a third party. We may not be able to obtain such a license on commercially acceptable terms, or at all.

International patent protection is uncertain.

Patent law outside the United States is uncertain and is currently undergoing review and revision in many countries. Further, the laws of some foreign countries may not protect our intellectual property rights to the same extent as U.S. laws. We may participate in opposition proceedings to determine the validity of our or our competitors foreign patents, which could result in substantial costs and diversion of our efforts.

We may not realize all of the anticipated benefits of the merger with Genesoft.

The success of our merger with Genesoft will depend, in part, on our ability to realize the anticipated synergies, cost savings and growth opportunities from integrating our business with the former business of Genesoft. Our success in realizing these benefits and the timing of this realization depends upon the successful integration of the former operations of Genesoft. The full integration of two independent companies, especially when one company is located on the West Coast and the other on the East Coast, is a complex, costly and time-consuming process. The difficulties of combining the operations of the companies and realizing the expected benefits of the merger include, among others:

- coordinating commercial and clinical development initiatives and staffs for FACTIVE and Ramoplanin;
- raising sufficient capital to fund the significant expenditures that are needed to launch and successfully commercialize FACTIVE and the further clinical development of Ramoplanin;

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- retaining key employees;
- consolidating research and development operations;
- consolidating corporate and administrative infrastructures and physical plant;
- integrating and managing the technology of two companies; and
- minimizing the diversion of management s attention from ongoing business concerns.

We cannot assure you that we will realize the full benefits anticipated by us to result from the merger. In addition, we may not have sufficient capital to fully implement our strategies following the merger which may cause a delay in the launch of FACTIVE tablets and could further prevent us from realizing the anticipated benefits of the merger.

Our debt obligations expose us to risks that could adversely affect our business, operating results and financial condition.

We have a substantial level of debt. As of December 31, 2004, after giving effect to the issuance and sale of the convertible notes during the second quarter of 2004, we had approximately $176 million of indebtedness outstanding (excluding trade payables and accrued liabilities). The level of our indebtedness, among other things, could:

- make it difficult for us to make payments on our debt outstanding from time to time;
- make it difficult for us to obtain any necessary financing in the future for working capital, capital expenditures, debt service, acquisitions or general corporate purposes;
- limit our flexibility in planning for or reacting to changes in our business;
- reduce funds available for use in our operations;
- impair our ability to incur additional debt because of financial and other restrictive covenants;
- make us more vulnerable in the event of a downturn in our business; or
- place us at a possible competitive disadvantage relative to less leveraged competitors and competitors that have better access to capital resources.

If we experience a decline in revenues due to any of the factors described in this report or otherwise, we could have difficulty making required payments on our indebtedness. If we are unable to generate sufficient cash flow or otherwise obtain funds necessary to make required payments, or if we fail to comply with the various requirements of our indebtedness, we would be in default, which would permit the holders of our indebtedness to accelerate the maturity of the indebtedness and could cause defaults under any indebtedness we may incur in the future. Any default under our indebtedness could have a material adverse effect on our business, operating results and financial condition.

Our ability to meet our debt service obligations will depend upon our future performance, which will be subject to financial, business and other factors affecting our operations, many of which are beyond our control.

RISKS RELATED TO OUR INDUSTRY

Health care insurers and other payers may not pay for our products or may impose limits on reimbursement.

Our ability to commercialize FACTIVE tablets, Ramoplanin and our future products will depend, in part, on the extent to which reimbursement for such products will be available from third-party payers, such as Medicare, Medicaid, health maintenance organizations, health insurers and other public and private payers. We cannot assure you that third-party payers will pay for such products or will establish and maintain price levels sufficient for realization of an appropriate return on our investment in product development. If adequate coverage and reimbursement levels are not provided by government and private payers for use of our products, our products may fail to achieve market acceptance and

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our results of operations may be materially adversely affected. In addition, in December 2003 President Bush signed into law new Medicare prescription drug coverage legislation. While we cannot yet predict the impact the new legislation could have on our ability to commercialize FACTIVE tablets, Ramoplanin and any future products, the new legislation could adversely affect our anticipated revenues and results of operations, possibly materially.

Many health maintenance organizations and other third-party payers use formularies, or lists of drugs for which coverage is provided under a health care benefit plan, to control the costs of prescription drugs. Each payer that maintains a drug formulary makes its own determination as to whether a new drug will be added to the formulary and whether particular drugs in a therapeutic class will have preferred status over other drugs in the same class. This determination often involves an assessment of the clinical appropriateness of the drug and sometimes the cost of the drug in comparison to alternative products. We cannot assure you that FACTIVE tablets, Ramoplanin or any of our future products will be added to payers formularies, whether our products will have preferred status to alternative therapies, nor whether the formulary decisions will be conducted in a timely manner. We may also decide to enter into discount or formulary fee arrangements with payers, which could result in our receiving lower or discounted prices for FACTIVE tablets, Ramoplanin or future products.

Wholesalers, Pharmacies and Hospitals may not provide adequate distribution for our Products.

Our ability to commercialize FACTIVE tablets, Ramoplanin and our future products, will depend, in part, on the extent to which we obtain adequate distribution of our products via wholesalers, pharmacies and hospital, as well as other customers. Wholesalers and larger retailers may be reluctant to stock and distribute Oscient products since we are not a large, well-established company. If we do not obtain adequate distribution of our products, the commercial launch of FACTIVE and our anticipated revenues and results of operations could be adversely affected.

If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, we could be forced to pay substantial damage awards.

The use of any of our product candidates in clinical trials, and the sale of any approved products, might expose us to product liability claims. We currently maintain, and we expect that we will continue to maintain, product liability insurance coverage in the amount of $10 million per occurrence and $10 million in the aggregate. Such insurance coverage might not protect us against all of the claims to which we might become subject. We might not be able to maintain adequate insurance coverage at a reasonable cost or in sufficient amounts or scope to protect us against potential losses. In the event a claim is brought against us, we might be required to pay legal and other expenses to defend the claim, as well as uncovered damage awards resulting from a claim brought successfully against us. Furthermore, whether or not we are ultimately successful in defending any such claims, we might be required to direct financial and managerial resources to such defense and adverse publicity could result, all of which could harm our business.

In addition, a product recall or excessive warranty claims (in any such case, whether arising from manufacturing deficiencies, labeling errors or other safety or regulatory reasons) could have an adverse effect on our product sales or require a change in the indications for which our products may be used.

RISKS RELATED TO THE SECURITIES MARKET

Our stock price is highly volatile.

The market price of our stock has been and is likely to continue to be highly volatile due to the risks and uncertainties described in this section of the exhibit, as well as other factors, including:

our ability to successfully commercialize FACTIVE tablets;

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- the revenues that we may derive from the sale of FACTIVE tablets, as compared to analyst estimates;
- the results of our clinical trials for Ramoplanin and additional indications for FACTIVE and the pace of our progress in those clinical trials;
- our ability to license or develop other compounds for clinical development;
- the timing of the achievement of our development milestones and other payments under our strategic alliance agreements;
- termination of, or an adverse development in, our strategic alliances;
- conditions and publicity regarding the biopharmaceutical industry generally;
- price and volume fluctuations in the stock market at large which do not relate to our operating performance; and
- comments by securities analysts, or our failure to meet market expectations.

Over the two-year period ending December 31, 2004 the closing price of our common stock as reported on the Nasdaq National Market ranged from a high of $7.01 to a low of $1.28. The stock market has from time to time experienced extreme price and volume fluctuations that are unrelated to the operating performance of particular companies. In the past, companies that have experienced volatility have sometimes been the subject of securities class action litigation. If litigation were instituted on this basis, it could result in substantial costs and a diversion of management s attention and resources. These broad market fluctuations may adversely affect the price if our securities, regardless of our operating performance.

Multiple factors beyond our control may cause fluctuations in our operating results and may cause our business to suffer.

Our revenues and results of operations may fluctuate significantly, depending on a variety of factors, including the following:

- the pace of our commercialization of FACTIVE tablets;
- the level of acceptance by physicians and third party payors of FACTIVE;
- the progress of our clinical trials for FACTIVE, Ramoplanin and our other product candidates;
- our success in concluding deals to acquire additional approved products and product candidates;
- the introduction of new products and services by our competitors;
- regulatory actions; and
- expenses related to, and the results of, litigation and other proceedings relating to intellectual property rights.

We will not be able to control many of these factors. In addition, if our revenues in a particular period do not meet expectations, we may not be able to adjust our expenditures in that period, which could cause our business to suffer. We believe that period-to-period comparisons of our financial results will not necessarily be meaningful. You should not rely on these comparisons as an indication of our future performance. If our operating results in any future period fall below the expectations of securities analysts and investors, our stock price may fall, possibly by a significant amount.

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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 $1,009,000 decrease in the fair value of our investments as of December 31, 2004. Our investment policy limits the amount of our credit exposure to any one issue, issuer, and type of instrument.

As of December 31, 2004 we did not have any financing arrangements that were not reflected in our balance sheet.

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.

In the quarter ended June 26, 2004, we issued $152,750,000 in principal amount of our 3.5% senior convertible promissory notes due April 2011. These notes are convertible into shares of our common stock at the option of the holders at a conversion price of $6.64 per share. We may not redeem the notes at our election before May 10, 2010. After this date, we can redeem all or a part of the notes for cash at a price equal to 100% of the principal amount of the notes to be redeemed plus accrued and unpaid interest. Upon the occurrence of a change of control or a termination of trading of our common stock (each as defined in the indenture for the notes), holders of our notes have the right to require us to repurchase all or any portion of their notes at a price equal to 100% of the principal amount plus accrued and unpaid interest. In addition, in the case of a cash purchase of our common stock, we may have an obligation to pay an additional make-whole premium to our note holders based on a formula set forth in the indenture

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 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

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Item 9A. Controls and Procedures

Conclusion Regarding The Effectiveness Of Disclosure Controls And Procedures

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, 2004 in connection with the preparation of this annual report. They concluded that the controls and procedures were effective as of the end of the period covered by this annual report.

MANAGEMENT S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). All internal controls over financial reporting, no matter how well designed, have inherent limitations. As a result of these inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those internal controls determined to be effective can provide only reasonable assurance with respect to reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in *Internal Control Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2004.

Our management s assessment of the effectiveness of our internal control over financial reporting as of December 31, 2004 has been audited by Ernst & Young LLP, our independent registered public accounting firm, as stated in their report which is included herein.

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders of

Oscient Pharmaceuticals Corporation

We have audited management s assessment, included in the accompanying Management s Report on Internal Control Over Financial Reporting, that Oscient Pharmaceuticals Corporation maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Oscient Pharmaceuticals Corporation s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management s assessment and an opinion on the effectiveness of the company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management s assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management s assessment that Oscient Pharmaceuticals Corporation maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Oscient Pharmaceuticals Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the COSO criteria**.**

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Oscient Pharmaceuticals Corporation as of December 31, 2004 and 2003, 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, 2004 and our report dated March 10, 2005 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts

March 10, 2005

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Item 9B. OTHER INFORMATION

None.

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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 May 25, 2005.

Item 10. Directors and Executive Officers of the Registrant

DIRECTORS AND EXECUTIVE OFFICERS

Information regarding our directors and executive officers may be found under the captions Election of Directors and Executive Officers in the Proxy Statement for our 2005 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

AUDIT COMMITTEE

We have a separately-designated standing Audit Committee established in accordance with Section 3(a)(58)(A) of the Exchange Act. Additional information regarding the Audit Committee may be found under the captions Board of Directors Meetings and Committee Meetings and Report of the Audit Committee in the Proxy Statement for our 2005 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

AUDIT COMMITTEE FINANCIAL EXPERT

The Board of Directors has determined that it has at least one Audit Committee Financial Expert (as defined by Item 401(h)(2) of Regulation S-K of the Exchange Act) on the Audit Committee of the Board of Directors, William S. Reardon. The Board of Directors has further determined that Mr. Reardon is independent from management within the meaning of Item 7(d)(3)(iv) of Schedule 14A under the Exchange Act.

SECTION 16(A) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Information regarding Section 16(a) Beneficial Ownership Reporting Compliance may be found under the caption Section 16(a) Beneficial Ownership Reporting Compliance in the Proxy Statement for our 2005 Annual Meeting of Stockholders. Such information is incorporated herein by reference

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.oscient.com), by sending a written request to Investor Relations, Oscient Pharmaceuticals Corporation, 1000 Winter Street, Suite 2200, Waltham, MA 02451, or by emailing investors@oscient.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.

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Item 11. Executive Compensation

Information with respect to this item may be found under the captions Directors Compensation, Compensation Committee Interlocks and Insider Participation, Executive Compensation, and Employment Agreements, in the Proxy Statement for our 2005 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Information with respect to this item may be found under the caption Security Ownership of Certain Beneficial Owners and Management in the Proxy Statement for our 2005 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions

Information with respect to this item may be found under the caption Certain Relationships and Related Transactions in the Proxy Statement for our 2005 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

Information with respect to this item may be found under the caption Principal Accountant Fees and Services in the Proxy Statement for our 2005 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

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PART IV

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

(a) FINANCIAL STATEMENTS See Index to Consolidated Financial Statements 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, MA[11]

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Exhibit No.	Description
10.6	Lease dated June 3, 1993 relating to certain property in Waltham, MA[11]
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]*

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Exhibit No.	Description
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)
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)
10.39	Employment Letter with Dominick Colangelo(38)
10.40	Employment Letter with Antonius Bunt(38)
12.1	Statement re: Computation of Ratios(38)
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm(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)

* 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.

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(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.

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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.

OSCIENT PHARMACEUTICALS CORPORATION

By: /s/ Steven M. Rauscher

Steven M. Rauscher

President and Chief Executive Officer

Dated: March 16, 2005

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 16, 2005
/s/ Stephen Cohen Stephen Cohen	Senior Vice President and Chief Financial Officer (Chief Financial and Accounting Officer)	March 16, 2005
/s/ David B. Singer David B. Singer	Chairman of the Board and Director	March 16, 2005
/s/ Luke Evnin Luke Evnin	Director	March 16, 2005
/s/ Robert J. Hennessey Robert J. Hennessey	Director	March 16 2005
/s/ Vernon R. Loucks, Jr. Vernon R. Loucks, Jr.	Director	March 16, 2005
/s/ William S. Reardon William S. Reardon	Director	March 16, 2005
/s/ Norbert G. Riedel	Director	March 16, 2005

Norbert G. Riedel		
/s/ Pamela J. Kirby	Director	March 16, 2005
Pamela Kirby		
/s/ David K. Stone	Director	March 16, 2005
David K. Stone		
/s/ John E. Voris	Director	March 16, 2005
John E. Voris		

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Oscient Pharmaceuticals Corporation

Index to Consolidated Financial Statements

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders of

Oscient Pharmaceuticals Corporation

We have audited the accompanying consolidated balance sheets of Oscient Pharmaceuticals Corporation (the Company) as of December 31, 2004 and 2003, 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, 2004. 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 the standards of the Public Company Accounting Oversight Board (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 Oscient Pharmaceuticals Corporation at December 31, 2004 and 2003, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Oscient Pharmaceuticals Corporation s internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated March 10, 2005 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts

March 10, 2005

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Oscient Pharmaceuticals Corporation

Consolidated Balance Sheets

December 31,	2004	2003
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 64,743,273	$ 20,969,292
Marketable securities (held-to-maturity)	94,908,700	4,595,740
Marketable securities (available-for-sale)		3,100,000
Restricted cash	5,386,250	
Interest receivable	1,708,360	138,189
Accounts receivable	4,223,412	257,389
Inventories	11,915,881	
Prepaid expenses and other current assets	5,898,546	120,852
Total Current Assets	188,784,422	29,181,462
Property and Equipment, at cost:		
Laboratory, scientific and marketing equipment		