

OSCIENT PHARMACEUTICALS CORP  
Form 10-K  
March 10, 2006  
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## SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

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### FORM 10-K

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(Mark one)

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

For the fiscal year ended: December 31, 2005  
OR

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

Commission file number: 0-10824

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## OSCIENT PHARMACEUTICALS CORPORATION

(Exact name of registrant as specified in its charter)

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Massachusetts  
(State or other jurisdiction)

of incorporation or organization)  
1000 Winter Street Suite 2200,

Waltham, Massachusetts  
(Address of principal executive offices)

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

04-2297484  
(IRS employer

identification number)

02451  
(Zip Code)

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

**None**

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

**Common Stock, \$.10 Par Value**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes  No

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer  Non-accelerated filer   
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of June 30, 2005, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was \$203,340,057 as reported on the National Association of Securities Dealers Automated Quotation National Market System. The number of shares outstanding of the registrant's common stock as of March 6, 2006 was 77,661,648.

Documents Incorporated By Reference. Portions of the registrant's proxy statement for use at its Annual Meeting to be held June 6, 2006 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**

#### **Item 1. Business**

##### **OVERVIEW**

We are a commercial-stage biopharmaceutical company committed to the clinical development and commercialization of new therapeutics to serve unmet medical needs. We currently promote two products in the United States. Our lead product is the fluoroquinolone antibiotic FACTIVE® (gemifloxacin mesylate) tablets, approved in the U.S. 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 and FACTIVE is currently promoted nationally by a sales team comprised of approximately 300 representatives. We also co-promote Auxilium Pharmaceuticals, Inc.'s marketed product, TESTIM gel, a topical 1% testosterone gel indicated for the treatment of male hypogonadism. Additionally, we are developing a novel antibiotic candidate, Ramoplanin, for the treatment of *Clostridium difficile*-associated disease.

##### **BUSINESS STRATEGY**

Our goal is to become a leading biopharmaceutical company focused on the clinical development and commercialization of new therapeutics. Our business strategy focuses on primary care physicians. We intend to commercialize products that will be used by primary care physicians in the community and in the hospital. The key elements of our strategy are as follows:

##### **Community-Based Primary Care**

###### ***Expanded Marketing and Further Development of FACTIVE Tablets***

Our primary business focus is the commercialization of FACTIVE in the U.S. for a five-day treatment of acute bacterial exacerbations of chronic bronchitis and a seven-day treatment of community-acquired pneumonia of mild to moderate severity. 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.

The FDA has recently accepted for filing our supplemental New Drug Application (sNDA) seeking marketing approval for the use of FACTIVE for the five-day treatment of CAP. The FDA granted a standard ten-month review period for the five-day CAP sNDA and is expected to act on the filing by the end of September 2006. The acceptance of the CAP sNDA for filing does not assure approval.

###### ***Building our Primary Care Business Through New Products***

In April 2005, we entered into a co-promotion agreement with Auxilium Pharmaceuticals, Inc. under which we and Auxilium co-promote in the United States TESTIM gel, a topical 1% testosterone gel indicated for the treatment of male hypogonadism. Pursuant to the agreement, we have the exclusive right to promote TESTIM gel jointly with Auxilium to primary care physicians. We continue to explore ways of expanding our primary care commercial offerings and product portfolio through co-promotion, licensing arrangements or acquisition of complementary products and product candidates.

###### ***Sublicensing Rights to FACTIVE Tablets in Territories Outside of the U.S.***

On February 6, 2006, we sublicensed the rights to commercialize FACTIVE tablets in Mexico to Pfizer, S.A. de C.V., a subsidiary of Pfizer Inc. We will continue to pursue similar partnering arrangements in Canada and in certain European countries to leverage FACTIVE's brand and commercial potential.

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### **Hospital Business**

Our lead product candidate is our novel antibiotic, Ramoplanin, to which we recently acquired worldwide rights from Pfizer Inc.'s wholly owned subsidiary, Vicuron Pharmaceuticals, Inc. We recently agreed with the FDA on a Special Protocol Assessment for the continued clinical development of Ramoplanin and are advancing the clinical program of Ramoplanin toward a Phase III program for the treatment of *Clostridium difficile*-associated disease. We also have a development-stage intravenous formulation of gemifloxacin, which we plan to pursue.

### **PHARMACEUTICAL PRODUCTS AND PROGRAMS: Community-Based Primary Care**

#### **Infectious Diseases Market**

Infectious diseases represent the second leading cause of death worldwide accounting for over 14 million deaths each year, with lower respiratory tract infections alone causing 3.9 million deaths annually. Bacterial infections are the sixth leading cause of death in the U.S. Anti-bacterials represent the largest segment of the anti-infective market, with an estimated \$30 billion in total worldwide sales.

The principal structural classes of antibiotics include beta-lactams, fluoroquinolones, macrolides, ketolides, 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. The late 1990s saw further development with newer generations of fluoroquinolones, the ketolides and two new classes: oxazolidinones and lipopeptides.

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**

*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 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; studies estimate that two-thirds are caused by bacteria. 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. Fluoroquinolones are frequently used to treat AECB due to their activity versus *H. influenzae* and *M. catarrhalis*, two of the most common causes of these infections. Newer fluoroquinolones have enhanced activity versus *S. pneumoniae*, another common cause of these infections.

*Community-Acquired Pneumonia:* Community-acquired pneumonia, or CAP, is a common and serious illness in the United States. The 4 to 5 million reported cases per year of CAP result in approximately 10 million physician visits, 1 million hospitalizations, 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 instance. 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

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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 licensed from LG Life Sciences 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. In April of 2004, FACTIVE received marketing approval in Canada for the treatment of AECB.

Within the antibiotic market, fluoroquinolones, a product class with close to \$3 billion in annual sales in the U.S. in 2005, 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 tablets represent an alternative choice for the treatment of certain respiratory tract infections.

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 0.032 µg/ml for *S. pneumoniae*. In clinical trials, FACTIVE was administered to approximately 8,000 patients and had a good overall safety and tolerability profile. FACTIVE has been the subject of over 200 scientific publications and has been mentioned in nearly 275 scientific articles. Among the research published are data indicating that a higher percentage of patients treated with FACTIVE remained free of AECB recurrences than those treated with a comparator agent over a six-month period following treatment.

*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.

*Clinical Efficacy:* The clinical program for FACTIVE has included 19 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. In these principal Phase III AECB studies 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%

FACTIVE tablets 5 days (320 mg): 86.0%

FACTIVE tablets 5 days (320 mg): 93.6%

Levofloxacin 7 days (500 mg): 85.1%

Clarithromycin 7 days (500 mg 2 times/day, or bid): 84.8%

Amoxicillin/clavulanate 7 days (500 mg/125 mg, 3 times/day, or tid): 93.2%

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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.

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.

FACTIVE has the lowest MIC<sub>90</sub> (0.032 µg/mL) for *S. pneumoniae*, one of the most prevalent pathogens found in lower respiratory tract infections, compared to the currently marketed fluoroquinolones.

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 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 achieves high concentration levels in lung and bronchial tissues and in secretions.

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 have been studied in approximately 8,000 patients in clinical trials and we estimate that to date, nearly 295,000 prescriptions have been written for FACTIVE since its launch in September 2004. 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 with treatment durations greater than seven days and patients less than 40 years of age, especially females. Since the launch of the drug, the post-marketing 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





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(2,500 patients) in patients with mild-to-moderate 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. This Phase IV trial was initiated in the fall of 2004 with expected completion within three to four years. In connection with the approval of FACTIVE tablets, the FDA has also required us to perform a utilization study to obtain data on the prescribing patterns and use of FACTIVE tablets for the first three years after initial marketing in the U.S. As part of this requirement, we furnish interim reports to the FDA on an annual basis on the number of prescriptions issued, including refills and the diagnoses for which the prescriptions are dispensed.

*Additional Development of Gemifloxacin:* Clinical trials of FACTIVE for the potential five-day treatment of mild to moderate community-acquired pneumonia (CAP) have been completed and the FDA has recently accepted for filing our supplemental New Drug Application (sNDA) seeking marketing approval for the use of FACTIVE for the five-day treatment of CAP. The FDA granted a standard ten-month review period for the five-day CAP sNDA and is expected to act on the filing by the end of September 2006. The acceptance of the CAP sNDA filing does not assure approval.

In the five-day CAP clinical trial, a five-day course of therapy with FACTIVE was shown to be as effective as the FDA-approved seven-day course of treatment, with both arms displaying excellent clinical response rates. Further, data showed that the bacteriological and radiologic success rates with five days of therapy were also non-inferior to the success rates with seven days of therapy. The multicenter, double-blind study enrolled 510 patients with CAP, with 469 patients comprising the per protocol group. Investigators measured clinical and bacteriological response at end of therapy as well as clinical, bacteriological and radiologic response at follow-up (two to three weeks post therapy). Clinical response at follow-up, the primary endpoint, in the per protocol group was 95% for the five-day treatment arm and 92% for the seven-day treatment arm [95% CI: -1.48, 7.42], demonstrating non-inferiority between the two groups. Further, clinical response at end of therapy in the per protocol group was 96% for the five-day group and 96% for the seven-day group [95% CI: -3.85, 3.42]. The study also yielded encouraging results for bacteriological response. Bacteriological response in the per protocol population was 91% for the five-day and seven-day groups at follow-up [95% CI: -6.89, 7.93] and 94% for the five-day group and 96% for the seven-day group [95% CI: -8.27, 3.25] at end of therapy. The study demonstrated radiologic response at follow-up in the per protocol population of 98% for the five-day arm and 93% for the seven-day arm [95% CI: -0.35, 7.91]. FACTIVE was well-tolerated in the study, with a low withdrawal rate due to adverse events: 1.2% for the five-day group and 2.0% for the seven-day group. The most common adverse event reported was a laboratory finding of elevated liver enzymes (increased ALT and increased AST). Analysis of all ALT/AST values demonstrated that the elevations were significantly associated with baseline ALT levels (elevated in many patients) with no significance or association with a particular treatment group. There was also no evidence of symptomatic hepatic events. In addition, the rate of drug-related rash in both treatment groups was low: 0.4% for the five-day arm and 2.8% for the seven-day arm. There were no withdrawals due to rash.

We are also in discussions with the FDA regarding an indication for acute bacterial sinusitis (ABS). Two double-blind, randomized, active-controlled clinical studies were conducted to examine the efficacy of FACTIVE 320 mg once daily for seven days in the treatment of patients with ABS. The results of these clinical trials showed comparable clinical success for patients treated with FACTIVE tablets versus those treated with comparator drugs. In addition, a double-blind, randomized, active-controlled clinical study comparing a seven-day treatment of FACTIVE with a five-day treatment of FACTIVE showed similar efficacy between both treatment arms. In November 2005, we submitted an sNDA to the FDA for the five-day treatment of ABS, however, the FDA refused to accept the sNDA for filing. In its refusal to file the sNDA for ABS, the FDA indicated that FACTIVE did not exhibit an acceptable risk versus benefit profile for the ABS indication. In addition, the FDA expressed the opinion that demonstrating an acceptable risk versus benefit profile for FACTIVE in ABS was not feasible, given the FDA's view of the potential risk of rash in those patients. Although we intend to continue our discussions with the FDA regarding the ABS indication, we cannot guarantee that the ABS indication will ever be approved by the FDA.

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*License Agreement with LG:* 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 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 for composition of matter expires in 2018. 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.

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 our anticipated commercial requirements for the FACTIVE bulk drug substance. LG Life Sciences currently supplies the FACTIVE bulk drug substance from its manufacturing facility in South Korea.

The agreement with LG Life Sciences also requires a minimum sales commitment over a period of time, which if not met, would result in the technology being returned to LG Life Sciences. Under this agreement, we are responsible, at our expense and through consultation with LG Life Sciences, for the clinical and commercial development of gemifloxacin in the countries covered by the license, including the conduct of clinical trials, the filing of drug approval applications with the FDA and other applicable regulatory authorities and the marketing, distribution and sale of gemifloxacin in our territory; provided, that LG Life Sciences has the right to co-promote the product, on terms to be negotiated, in our territory commencing in 2008 and for periods thereafter, in which case our royalty obligations to LG Life Sciences would cease. Pursuant to an amendment dated March 31, 2005 as further described below, LG Life Sciences' right to co-promote in the U.S. will terminate upon our reaching a certain level of sales.

We are obligated to pay a royalty on sales of FACTIVE in North America and the territories covered by the license in Europe. These royalty obligations expire with respect to each country covered by the agreement on the later of the expiration of the patents covering FACTIVE in such country or ten years following the first commercial sale of FACTIVE in such country. We are also obligated to make aggregate milestone payments of up to \$31 million (not including upfront payments) to LG Life Sciences (including milestone payments required by the amendments described below) upon achievement of additional regulatory approvals and sales thresholds and upon consummation of sublicense agreements.

On March 31, 2005, we amended our license and option agreement with LG Life Sciences. As part of the amendment of the agreement, we made a one time, upfront payment of \$2 million to LG Life Sciences which was recorded to general and administrative expense in the three month period ended March 31, 2005 and agreed to make certain additional milestone payments upon obtaining regulatory approvals and sales thresholds. The amended agreement also includes a reduction of future royalties payable to LG Life Sciences at certain FACTIVE revenue levels in territories covered by the agreement.

We further amended our agreement with LG Life Sciences on February 3, 2006, pursuant to which LG Life Sciences agreed to a reduction of future royalties payable for sales of FACTIVE tablets in Mexico and Canada and the termination of LG Life Sciences' co-promotion rights in these countries if we consummate sublicense agreements in such countries prior to dates specified in the amendment. The modified agreement also calls for additional milestone payments to be made to LG Life Sciences upon consummation of sublicense agreements in Mexico and Canada as well as upon receipt of regulatory approval of FACTIVE in each of such countries.

Gross margins of FACTIVE sales in the U.S., after standard product costs and royalties but excluding amortization of intangible assets, are expected to be in the 70%-75% range for the first two years after launch and in the 65%-70% percent range thereafter. As a result of the March amendment to the LG agreement discussed above, gross margins may return to the 70%-75% range if significantly higher sales of FACTIVE are achieved, which would require a significant expansion of the sales effort.

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*Partnership With Pfizer, S.A. de C.V.:* On February 6, 2006, we entered into a Sublicensing and Distribution Agreement with Pfizer, S.A. de C.V. (Pfizer Mexico), pursuant to which we sublicensed our rights to sell FACTIVE tablets in Mexico to Pfizer Mexico. Pfizer Mexico is responsible for obtaining regulatory approval for FACTIVE in Mexico. In exchange for those rights, Pfizer Mexico has agreed to pay us an up-front payment, milestone payments upon obtaining certain regulatory approvals and sales goals as well as royalties on future sales. These royalty rates are subject to reduction upon expiration of certain patents in Mexico for FACTIVE or if a generic form of gemifloxacin has a material impact on Pfizer Mexico's sales volumes in Mexico. Pfizer Mexico is obligated to exclusively purchase from us, and we must exclusively supply, all active pharmaceutical ingredient for FACTIVE. The agreement with Pfizer Mexico may be terminated by either party upon the occurrence of certain termination events, including Pfizer Mexico's right to terminate at any time after the first anniversary of launch of FACTIVE tablets in Mexico upon six months prior written notice. Upon termination of the Pfizer Agreement, Pfizer Mexico is obligated to assign any and all rights to regulatory approvals in Mexico to us or our designee.

### **Co-Promotion of TESTIM**

On April 11, 2005, we entered into a co-promotion agreement with Auxilium Pharmaceuticals, Inc. under which we and Auxilium will co-promote in the United States Auxilium's marketed product, TESTIM gel, a topical 1% testosterone gel indicated for the treatment of male hypogonadism. Pursuant to the agreement, we have the exclusive right to promote TESTIM gel jointly with Auxilium to primary care physicians. The initial term of the agreement ends on April 30, 2007. We may extend the agreement for two consecutive two-year periods provided that we have met certain milestones for each extension related to physician detailing, market share and gross sales. If these milestones are met and we do not elect to terminate the co-promotion agreement, the first extension period will end on December 31, 2008 and the second extension period will end on April 30, 2011.

Both organizations have established and continue to develop a promotion plan which sets forth the responsibilities of both parties with respect to the marketing and promotion of TESTIM gel in the U.S. primary care physician market. We are obligated to share TESTIM promotional expenses to this physician market equally with Auxilium. Each party will be responsible for the costs associated with its own sales force. In addition, Auxilium is obligated to pay us a co-promotion fee based on a specified percentage of the gross profit from TESTIM sales attributable to primary care physicians in the U.S. that exceeds a specified sales threshold. The specific percentage is based upon TESTIM sales levels attributable to primary care physicians and the marketing expenses incurred by us in connection with the promotion of TESTIM gel under the co-promotion agreement. The co-promotion agreement can be terminated by either party upon the occurrence of certain termination events, including approval and sale of a generic form of TESTIM gel in the United States, in which case Auxilium is obligated to pay to us a specified percentage of the profits for product sales for the following two years. Also, we have been granted the exclusive option to co-promote any future Auxilium product candidate that treats male hypogonadism and contains testosterone as the active ingredient. The terms and conditions of such future agreement would be negotiated in good faith by the parties at the time the option is exercised.

### **PHARMACEUTICAL PRODUCTS AND PROGRAMS: Hospital-Based**

#### **Hospital-Acquired Infections**

*Clostridium difficile*-Associated Disease (CDAD): CDAD, a serious form of colitis caused by toxins produced by the Gram-positive bacterium *Clostridium difficile* (*C. difficile*), is the most commonly recognized microbial cause of diarrhea, resulting from high rates of colonization in hospitalized patients and the frequent use of antimicrobials. About 3% of healthy adults and 16 - 35% 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. Severe 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 increased 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.

Two studies recently published in *The New England Journal of Medicine* (December 2005) describe a new strain of *C. difficile*, one that produces 16–23 times more toxins *in vitro* than do other strains thus potentially contributing to its virulence. Particularly concerning about this new strain are the very high incidence and mortality rates. Data support the concept that this highly virulent strain is causing epidemic disease at certain locations and is associated with more frequent and more severe disease.

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 U.S. and Canadian rights to Ramoplanin from Vicuron Pharmaceuticals Inc. (Vicuron), a wholly-owned subsidiary of Pfizer Inc., and on February 3, 2006, acquired worldwide rights from Vicuron, assuming full control of Ramoplanin manufacturing, development and commercialization. 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*, including the recent epidemic strains. 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 *in vitro* to date. Ramoplanin has a unique profile that may make it particularly well-suited 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 patients in 24 U.S. sites. The trial compared two doses of Ramoplanin (200 mg and 400 mg twice daily) to vancomycin (125 mg four times daily). 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. While the study did not meet its primary endpoint, non-inferiority at the test-of-cure visit, the response rates for all three arms were comparable. 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 recently agreed with the FDA to a Special Protocol Assessment (SPA) regarding the specific components of the Phase III program that, if completed successfully, would support regulatory approval for the indication. According to the agreement reached with the FDA, the required clinical development program will be comprised of two pivotal Phase III trials. The two non-inferiority studies will enroll, in each trial, approximately 490 patients diagnosed with CDAD, from centers in the United States, Canada and other parts of the world. Each patient will be randomly assigned to one of two treatment arms, in a double-blind fashion: Ramoplanin 200 mg twice daily or vancomycin 125 mg four times daily for ten days. The primary endpoint will be the response rate at end of therapy. We are working to establish a long-term source of commercial supply of Ramoplanin prior to the commencement of the Phase III program.

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*Potential Competitive Advantages:* We believe the potential competitive advantages of Ramoplanin are:

Ramoplanin belongs to a novel class of antibiotics and there have been no observed cases of bacterial resistance or cross-resistance with other antibiotics to date.

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 or in the elimination of normal, healthy bacteria.

Along with its activity against *C. difficile*, Ramoplanin has demonstrated *in vitro* activity against methicillin-resistant *Staphylococcus aureus* (MRSA) and VRE. Both organisms are associated with causing serious infections.

*Acquisition of Expanded Rights:* We previously licensed our rights to Ramoplanin from Vicuron pursuant to a License Agreement which provided us with exclusive rights to develop and market oral Ramoplanin in the U.S. and Canada. On February 3, 2006, we entered into an agreement with Vicuron, a wholly owned subsidiary of Pfizer Inc., whereby we acquired worldwide rights and assumed full control of Ramoplanin manufacturing, development and commercialization. In exchange for the assignment of the rights under this acquisition agreement, we made a one-time, up-front payment to Pfizer and will make additional milestone payments for regulatory filings and approvals in various countries. We will also pay mid-single-digit to low double-digit royalties to Pfizer on net sales of Ramoplanin dependent upon the territory. Pursuant to the acquisition agreement, we assumed all responsibility for manufacture of Ramoplanin and are currently in discussions with potential third-party manufacturers for Ramoplanin in order to secure long term product supply.

### **Intravenous FACTIVE**

An intravenous formulation of gemifloxacin has also been studied. We expect to complete additional formulation development prior to initiating a Phase I bioequivalence study. Pending successful outcomes, we believe a single Phase III study would be required before seeking marketing approval from the FDA.

### **PHARMACEUTICAL PRODUCTS AND PROGRAMS: Pre-clinical programs**

In August 2002, we entered into a research and license agreement with 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 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 advancement of this program is contingent on securing a development partnership with another organization.

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, including the rights to potential future milestone and royalty payments.



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### **PATENTS AND PROPRIETARY TECHNOLOGY**

Our success will depend, in part, on our ability to obtain commercially valuable patent claims and protect our intellectual property. To that end, our policy is to protect our proprietary technology primarily through patents. We currently own or license approximately 69 issued U.S. patents, approximately 81 pending U.S. patent applications, 156 issued foreign patents and approximately 193 pending foreign patent applications. These patents and patent applications primarily relate to (1) the chemical composition, use, and method of manufacturing FACTIVE, (2) metalloenzyme inhibitors, their uses and their targets, (3) anti-infective compounds and their uses, and (4) the field of human and pathogen genetics. 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-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. 5,869,670 granted February 9, 1999, relating to 7-(4-aminomethyl-3-methyloxyiminopyrrolidin-1-yl)-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1, 8-naphthyridine-3-carboxylic acid; licensed from LG Life Sciences; expiring June 15, 2015;

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

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

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

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

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

U.S. Patent No. 6,723,734 granted April 20, 2004, relating to the salt of naphthyridine 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.

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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.



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Under our license agreement with LG Life Sciences, we obtained an exclusive license to develop and market gemifloxacin in certain territories. This license covers 18 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 its 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 a patent term extension application covering the regulatory review process for one of the principal patents, U.S. Patent 5,776,944, expiring in 2015. If granted, this extension would extend the exclusivity period through 2017.

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.

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.

The patents to Ramoplanin that we recently acquired from 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 years of data exclusivity under the Hatch-Waxman Act in the U.S. and the ten years of market exclusivity in Europe available through the European Commission.

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.

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<sup>®</sup> (levofloxacin), a product of Ortho-McNeil Pharmaceutical, Inc., Tequin<sup>®</sup> (gatifloxacin), a product of Bristol-Myers Squibb Company, and Cipro<sup>®</sup> (ciprofloxacin) and Avelox<sup>®</sup> (moxifloxacin), both products of Bayer Corporation;

macrolides such as Biaxin<sup>®</sup> (clarithromycin), a product of Abbott Laboratories and Zithromax<sup>®</sup> (azithromycin), a product of Pfizer Inc., as well as generic equivalents of Zithromax;

Ketek<sup>®</sup> (telithromycin), a ketolide from Sanofi-Aventis Pharmaceuticals; and

penicillins such as Augmentin<sup>®</sup> (amoxicillin/clavulanate potassium), a product of GlaxoSmithKline, as well as generic equivalents of this product.

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

The primary competition for TESTIM gel for the treatment of male hypogonadism is ANDROGEL<sup>®</sup>, marketed by Solvay Pharmaceuticals. ANDROGEL was launched approximately three years before TESTIM gel and, according to NDC, has a much larger share of the testosterone gel market than TESTIM gel and also accounted for approximately 55% of total testosterone prescriptions for the twelve months ended December 31, 2005. TESTIM gel also competes with other forms of testosterone replacement therapies, or TRT, such as oral treatments, patches, injectables and a buccal tablet. Generally, testosterone gels are more expensive than patches and injectables. ANDRODERM<sup>®</sup> is a transdermal testosterone patch marketed by Watson Pharmaceuticals. ANDRODERM is the leading patch product and accounted for approximately 10% of total testosterone prescriptions for the twelve months ended December 31, 2005. Other new treatments are being sought for TRT which may compete with TESTIM gel.

We are also aware that Watson Pharmaceuticals filed an abbreviated New Drug Application (ANDA) for generic ANDROGEL which was approved by the FDA on January 27, 2006. Par Pharmaceutical has also filed an ANDA with the FDA for generic ANDROGEL for which its partner, Paddock Laboratories, received tentative approval on November 1, 2004. Solvay Pharmaceuticals has filed patent infringement lawsuits against these two companies. The launch of Watson's generic version of ANDROGEL, the final approval of the Par ANDA or the resolution of the ongoing patent infringement lawsuit in favor of Watson and/or Par would result in increased competition for TESTIM gel at lower prices.

Ramoplanin is in clinical development for the treatment of *Clostridium difficile*-associated disease (CDAD). We are aware of two products currently utilized in the marketplace Vancocin<sup>®</sup> pulvules (vancomycin), a product marketed by ViroPharma, and metronidazole, a generic product for treatment of this indication. We are also aware of at least eight companies with products in development for the treatment of CDAD. It is also possible that other companies are developing competitive products for this indication.

Additionally, we are aware that Vicuron and Novartis AG are jointly developing PDF inhibitor agents that may compete with any PDF products developed by our company.

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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 gain access to new products via co-promotion agreements or product acquisitions,

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 legacy genomics discoveries.

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 us and our licensees will vary depending on the nature of the product. Virtually all of our pharmaceutical products, including expanded uses of our 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,

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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.

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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-to-moderate severity and acute bacterial exacerbations of chronic bronchitis. Our most advanced product candidate, Ramoplanin, currently being studied for the treatment of *Clostridium difficile*-associated disease, will be regulated by the Center for Drug Evaluation and Research (CDER).

TESTIM gel contains testosterone which is listed by the U.S. Drug Enforcement Agency, or DEA, as a Schedule III substance under the Controlled Substances Act of 1970. The DEA classifies substances as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. Scheduled substances are subject to DEA regulations relating to manufacturing, storage, distribution and physician prescription procedures. Auxilium must register annually with the DEA to manufacture, distribute, dispense, import, export, and conduct research using controlled substances. State controlled substance laws also require registration for similar activities. In addition, the DEA requires entities handling controlled substances to maintain records and file reports, follow specific labeling and packaging requirements, and provide appropriate security measures to control against diversion of controlled substances. Failure to follow these requirements can lead to significant civil and/or criminal penalties and possibly even lead to a revocation of a DEA registration.

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.

As a post-marketing study commitment, the FDA 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 includes 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 measures of 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 tablets, the FDA has also required us to perform a utilization study to obtain data on the prescribing patterns and use of FACTIVE tablets for the first three years after initial marketing in the U.S. As part of this requirement, we furnish interim reports to the FDA annually 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 utilization study that we are required to provide to the FDA, as well as other safety information arising out of post-marketing safety surveillance, 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 and Patheon Pharmaceuticals Inc. (our third party finished-product manufacturer for FACTIVE tablets), 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 the 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.

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### **SALES AND MARKETING**

We have rights to market FACTIVE tablets 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, and co-promote Auxilium's testosterone product, TESTIM gel, to primary care physicians in the U.S.

We are selling FACTIVE and promoting TESTIM gel through our own sales and marketing organization in the U.S. Our sales representatives focus on high-prescribing primary care physicians and opinion leaders who represent approximately 40% of the total respiratory tract infection prescription universe. We began selling FACTIVE tablets in September 2004 with an initial sales force of 100 representatives and, as of December 31, 2005, had an approximately 250 person sales force. Additionally, we currently supplement the Oscient sales force with approximately 50 contract sales representatives, hired by Innovex Inc., the contract sales arm of Quintiles Transnational Corp. These additional sales representatives provide double coverage in 50 high potential territories to grow the FACTIVE physician prescribing base. We have also built a team of professionals with experience in medical education, insurance and government reimbursement, medical affairs, marketing, advertising and scientific communications.

On February 6, 2006, we sublicensed our rights to sell FACTIVE tablets in Mexico to Pfizer, S.A. de C.V. (Pfizer Mexico), and Pfizer Mexico is responsible for obtaining regulatory approval for FACTIVE in Mexico. Pfizer Mexico is the largest pharmaceutical company in Mexico, employing 2,270 employees, including 1,000 sales representatives specializing in six therapeutic areas.

We believe that the commercial success of FACTIVE tablets in territories outside of the U.S. will require the additional resources that a pharmaceutical marketing partner would provide. We anticipate that we will rely upon future partners 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.

### **MANUFACTURING**

Under the terms of our agreement with LG Life Sciences, LG Life Sciences has agreed to supply and we are obligated to purchase from LG Life Sciences all of our anticipated commercial requirements for FACTIVE bulk drug. LG Life Sciences is expected to supply the FACTIVE bulk drug substance from its manufacturing facility in South Korea. Patheon Pharmaceuticals Inc. currently provides the manufacture of finished products of FACTIVE sold in the U.S. With respect to our sublicense of commercialization rights in Mexico to Pfizer, S.A. de C.V. (Pfizer Mexico), Pfizer Mexico must purchase all of its anticipated commercial requirements for FACTIVE bulk drug from us, but has the option to receive finished FACTIVE product from us or to fill and finish the final tableted FACTIVE product at its manufacturing facilities in Mexico.

The co-promotion agreement for TESTIM gel provides that Auxilium is responsible for the manufacture and distribution of TESTIM gel. TESTIM gel is currently manufactured for Auxilium by DPT Laboratories. Auxilium's contract with DPT Laboratories to manufacture TESTIM gel expires on December 31, 2010. Although Auxilium is currently in the process of qualifying a back-up supplier to manufacture TESTIM gel, there is currently no alternative manufacturer of TESTIM gel. Auxilium also relies on third party suppliers for their supply of testosterone and pentadecalactone, or CPD, two key ingredients of TESTIM gel. Testosterone is available to Auxilium from only two sources. Auxilium relies exclusively on one outside source for their supply of CPD. Auxilium does not have any agreements with these suppliers regarding these key ingredients.

Pursuant to our recent acquisition of worldwide rights to Ramoplanin, we are responsible for the manufacture of both the active pharmaceutical ingredient and finished dosage form of the product. We are

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currently in discussions with a long term supplier for the Ramoplanin active pharmaceutical ingredient for our clinical trial program and future commercialization. We also plan to use a contract manufacturer to produce the final dosage to support such activities

**HUMAN RESOURCES**

As of December 31, 2005, we had 329 full-time equivalent employees. Forty eight of our employees held advanced degrees including: M.D.s, Ph.D.s, MBAs, Juris Doctors, PharmD.s or other Masters degrees. In addition, we had 50 sales representatives in a contract sales force, employed by Innovex, the contract sales arm of Quintiles Transnational Corp. None of our employees are covered by a collective bargaining agreement and we consider our relations with our employees to be good.

**OUR EXECUTIVE OFFICERS AND DIRECTORS**

<b>Name</b>	<b>Age</b>	<b>Position</b>
Steven M. Rauscher	52	Chief Executive Officer, President and Director
Stephen Cohen	59	Senior Vice President & Chief Financial Officer
Dominick Colangelo	42	Executive Vice President, Corporate Development & Operations
David K. Stone	49	Chairman of the Board and Director
Luke B. Evin	42	Director
Robert J. Hennessey	64	Director
Pamela J. Kirby	52	Director
Gary Patou	47	Director
William S. Reardon	59	Director
Norbert G. Riedel	48	Director
David B. Singer	43	Director
John E. Voris	58	Director

**AVAILABILITY OF INFORMATION**

We maintain a website with the address [www.oscient.com](http://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.

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**Item 1A. 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 \$88,593,000 for the fiscal year ended December 31, 2005 and had an accumulated deficit of approximately \$337,428,000. The losses have resulted primarily from costs incurred in research and development, including our clinical trials, from sales and marketing, and from general and administrative costs associated with our operations and product sales of FACTIVE tablets. These costs have exceeded our revenues which to date have been generated principally from sales of FACTIVE, co-promotion revenues based on the sale of TESTIM gel, 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 continue the co-promotion of TESTIM gel and in research and development in connection with clinical trials and formulation activities to support the existing labeling of FACTIVE tablets, the expansion of FACTIVE labeling claims and the development of Ramoplanin. 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 and TESTIM.**

FACTIVE tablets and TESTIM gel are currently our only commercial products and we expect that they 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. TESTIM gel has been approved by the FDA for the treatment of male hypogonadism. The commercial success of FACTIVE and TESTIM 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 products used, or currently being developed, to treat CAP and AECB, in the case of FACTIVE tablets, or male hypogonadism, in the case of TESTIM gel. The commercial success of TESTIM gel is also dependent, in part, on the marketing and detailing efforts of Auxilium, which efforts are beyond our control. If FACTIVE and TESTIM are not commercially successful, we will have to find additional sources of funding or curtail or cease operations.

**We will likely 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 through the end of 2006. We will likely 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 or other strategic financings or agreement with customers or vendors. In order to facilitate the raising of additional funds, we have filed a shelf registration statement that allows us to sell up to \$100,000,000 of our common stock. 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



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the FACTIVE, TESTIM and Ramoplanin commercial and clinical development programs. 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 continue to develop marketing and sales capabilities to successfully commercialize FACTIVE tablets, TESTIM and our other product candidates.**

FACTIVE tablets are our first FDA approved product. To date, we still have limited marketing and sales experience. The launch of FACTIVE occurred in September of 2004 and the co-promotion of TESTIM gel began in May 2005. The continued development of these marketing and sales capabilities, including the expansion of our sales force, will require significant expenditures, management resources and time. Further, as part of this development, we may seek to establish a co-promotion partnership in the future to expand FACTIVE commercialization in the U.S. or in our other licensed territories and/or acquire additional products for our expanded sales force. However, there is no assurance that we will be able to enter into a co-promotion agreement or acquire new products on favorable terms or at all. Failure to successfully establish sufficient sales and marketing capabilities in a timely and regulatory compliant manner or to find suitable sales and marketing partners may adversely affect our business and results of operations.

### **Our product and 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<sup>®</sup> (levofloxacin), a product of Ortho-McNeil Pharmaceutical, Inc., Tequin<sup>®</sup> (gatifloxacin), a product of Bristol-Myers Squibb Company, and Cipro<sup>®</sup> (ciprofloxacin) and Avelox<sup>®</sup> (moxifloxacin), both products of Bayer Corporation;

macrolides such as Biaxin<sup>®</sup> (clarithromycin), a product of Abbott Laboratories and Zithromax<sup>®</sup> (azithromycin), a product of Pfizer Inc., as well as generic equivalents of Zithromax;

Ketek<sup>®</sup> (telithromycin), a ketolide from Sanofi-Aventis Pharmaceuticals; and

penicillins such as Augmentin<sup>®</sup> (amoxicillin/clavulanate potassium), a product of GlaxoSmithKline, as well as generic equivalents of this product.

Many generic antibiotics are also currently prescribed to treat these infections. Moreover, a number of the antibiotic products that are competitors of FACTIVE tablets have gone or will be going off patent at dates ranging from 2003 to 2015. As these competitors lose patent protection, their manufacturers will likely decrease their promotional efforts. However, 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.

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The primary competition for TESTIM gel for the treatment of male hypogonadism is ANDROGEL<sup>®</sup>, marketed by Solvay Pharmaceuticals. ANDROGEL was launched approximately three years before TESTIM and, according to NDC, has a much larger share of the testosterone gel market than TESTIM gel and also accounted for approximately 55% of total testosterone prescriptions for the year ended December 31, 2005. TESTIM gel also competes with other forms of testosterone replacement therapies, or TRT, such as oral treatments, patches, injectables and a buccal tablet. Generally, testosterone gels are more expensive than patches and injectables. ANDRODERM<sup>®</sup> is a transdermal testosterone patch marketed by Watson Pharmaceuticals. ANDRODERM is the leading patch product and accounted for approximately 10% of total testosterone prescriptions for the year ended December 31, 2005. Other new treatments are being sought for TRT which may compete with TESTIM gel.

We are also aware that Watson Pharmaceuticals filed an abbreviated New Drug Application (ANDA) for generic ANDROGEL which was approved by the FDA on January 27, 2006. Par Pharmaceutical has also filed an ANDA with the FDA for generic ANDROGEL for which its partner, Paddock Laboratories, received tentative approval on November 1, 2004. Solvay Pharmaceuticals has filed patent infringement lawsuits against these two companies. The launch of Watson's generic version of ANDROGEL, the final approval of the Par ANDA or the resolution of the ongoing patent infringement lawsuit in favor of Watson and/or Par would result in increased competition for TESTIM gel at lower prices.

Ramoplanin is in clinical development for the treatment of *Clostridium difficile*-associated disease (CDAD). We are aware of two products currently utilized in the marketplace Vancocin<sup>®</sup> pulvules (vancomycin), a product marketed by ViroPharma, and metronidazole, a generic product for treatment of this indication. We are also aware of at least eight companies with products in development for the treatment of CDAD. It is also possible that other companies are developing competitive products for this indication.

Additionally, we are aware that Vicuron and Novartis AG are jointly developing PDF inhibitor agents that may compete with any PDF products developed by our company.

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, clinical 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 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 seven-day treatment of community-acquired pneumonia of mild to moderate severity (CAP) and the five-day treatment of acute bacterial

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exacerbations of chronic bronchitis (AECB). The original owner of rights to FACTIVE in the U.S. submitted a New Drug Application for FACTIVE for the treatment of several indications, including ABS, and received a non-approvable letter in December 2000. In November of 2005, we submitted a supplemental New Drug Application (sNDA) to the FDA seeking approval for the use of FACTIVE for the five-day treatment of ABS and the five-day treatment of CAP. On January 19, 2006, the FDA accepted for filing our sNDA for five-day CAP but refused to accept the sNDA filing for ABS. In its refusal to accept the sNDA filing for ABS, the FDA indicated that FACTIVE did not exhibit an acceptable risk versus benefit profile for the ABS indication. In addition, the FDA expressed the opinion that demonstrating an acceptable risk versus benefit profile for FACTIVE in ABS was not feasible, given the FDA's view of the potential risk of rash in those patients. Although we continue our discussions with the FDA regarding the ABS indication, we cannot guarantee the timing to address the FDA's concerns or whether the ABS indication will ever be approved. The FDA has granted a standard ten-month review period for the five-day CAP sNDA. We cannot be certain whether additional data will be required, if we will be required to conduct additional clinical trials or if the five-day CAP sNDA will ultimately be approved. In order to market FACTIVE for other indications, we may need to conduct additional clinical trials, obtain positive results from those trials and obtain FDA approval for such proposed indications. If we are unsuccessful in expanding the approved indications for the use of FACTIVE, the size of the commercial market for FACTIVE will be limited.

**Seasonal fluctuations in demand for FACTIVE may cause our operating results to vary significantly from quarter to quarter.**

We expect demand for FACTIVE to be higher between November 1 and March 31 as the incidence of respiratory tract infections, including CAP and AECB, tend to increase during the winter months. As a result, we expect our sales of FACTIVE to be higher during this season. In addition, fluctuations in the severity of the annual respiratory tract infection season may cause our product sales to vary from year to year. Due to these seasonal fluctuations in demand, our results in any particular quarter may not be indicative of the results for any other quarter or for the entire year.

**We as well as our partners are subject to numerous complex regulatory requirements and failure to comply with these regulations, or the cost of compliance with these regulations, may harm our business.**

The testing, development and manufacturing and distribution of our products are subject to regulation by numerous governmental authorities in the U.S., Europe, Mexico and elsewhere. These regulations govern or affect the testing, manufacture, safety, labeling, storage, record-keeping, approval, distribution, advertising and promotion of FACTIVE, TESTIM, Ramoplanin and our other product candidates, as well as safe working conditions and the experimental use of animals. Noncompliance with any applicable regulatory requirements can result in refusal of the government to approve products for marketing, criminal prosecution and fines, recall or seizure of products, total or partial suspension of production, prohibitions or limitations on the commercial sale of products or refusal to allow the entering into of federal and state supply contracts. The U.S. government agencies include, but are not limited to, the FDA, the Office of Inspector General and the Department of Justice. Our corporate compliance program cannot ensure that we are in compliance with all applicable laws and regulations, and a failure to comply with such regulations or a failure to prevail in litigation related to noncompliance could harm our business.

The FDA and comparable governmental authorities have the authority to withdraw product approvals that have been previously granted. Currently, there is a substantial amount of congressional and administrative review of the FDA and the regulatory approval process for drug candidates in the U.S. As a result, there may be significant changes made to the regulatory approval process in the U.S. In addition, the regulatory requirements relating to the manufacturing, testing, and promotion, marketing and distribution of our products may change in the U.S. or the other jurisdictions in which we may have obtained or be seeking regulatory approval for our products or product candidates. Such changes may increase our costs and adversely affect our operations.

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In addition, pharmaceutical companies have faced lawsuits and investigations pertaining to violations of health care fraud and abuse laws, such as the federal false claims act, the federal anti-kickback statute, and other state and federal laws and regulations. While we have developed and implemented a corporate compliance program based upon what we believe are current best practices, we cannot guarantee that this program will protect us from future lawsuits or investigations.

Failure to comply with or changes to the regulatory requirements that are applicable to FACTIVE, TESTIM or our other product candidates may result in a variety of consequences, including the following:

restrictions on our products or manufacturing processes;

warning letters regarding promotional and marketing materials and activities;

withdrawal of FACTIVE, TESTIM or a product candidate from the market;

voluntary or mandatory recall of FACTIVE, TESTIM or a product candidate;

fines against us or our partners;

suspension or withdrawal of regulatory approvals for FACTIVE, TESTIM or a product candidate;

suspension or termination of any of our ongoing clinical trials of a product candidate;

refusal to permit import or export of our products;

refusal to approve pending applications or supplements to approved applications that we or our partners submit;

denial of permission to file an application or supplement in a jurisdiction;

product seizure; and

injunctions or the imposition of civil or criminal penalties against us or our partners.

**Testosterone is classified by the U.S. Drug Enforcement Agency as a controlled substance and our failure or Auxilium's failure to comply with these heightened regulations could harm our business.**

TESTIM gel contains testosterone which is listed by the U.S. Drug Enforcement Agency, or DEA, as a Schedule III substance under the Controlled Substances Act of 1970. The DEA classifies substances as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. Scheduled substances are subject to DEA regulations relating to manufacturing, storage, distribution and physician prescription procedures. Auxilium must register annually with the DEA to manufacture, distribute, dispense, import, export, and conduct research using controlled substances. State controlled substance laws also

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require registration for similar activities. In addition, the DEA requires entities handling controlled substances to maintain records and file reports, follow specific labeling and packaging requirements, and provide appropriate security measures to control against diversion of controlled substances. Failure to follow these requirements can lead to significant civil and/or criminal penalties and possibly even lead to a revocation of a DEA registration.

In addition, products containing controlled substances may generate public controversy. As a result, these products may have their marketing rights or regulatory approvals withdrawn. Political pressures and adverse publicity could lead to delays in, and increased expenses for, and limit or restrict the marketing of TESTIM gel. Such delays, restrictions or expenses could harm our business.

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### **If testosterone replacement therapies are perceived to create or do create health risks, sales of TESTIM may be adversely affected.**

Recent studies of female hormone replacement therapy products have reported an increase in health risks. As a result of such studies, some companies that sell or develop female hormone replacement products have experienced decreased sales of these products, and in some cases, a decline in the value of their stock. Publications have, from time to time, suggested potential health risks associated with testosterone replacement therapy, or TRT. Potential health risks were described in various articles, including a 2002 article published in *Endocrine Practice* and a 1999 article published in the *International Journal of Andrology*. The potential health risks detailed were fluid retention, sleep apnea, breast tenderness or enlargement, increased red blood cells, development of clinical prostate disease, increased cardiovascular disease risk and the suppression of sperm production. It is possible that studies on the effects of TRT could demonstrate these or other health risks. This, as well as negative publicity about the risks of hormone replacement therapy, including TRT, could adversely affect patient or prescriber attitudes and impact TESTIM sales.

### **Sales of TESTIM will be highly dependent upon physician acceptance of testosterone replacement therapy for the treatment of hypogonadism.**

TESTIM gel is a testosterone replacement therapy, or TRT, approved for the treatment of hypogonadism, a disorder that affects approximately 20% of the U.S. male population over age 50. However, only about 5% of hypogonadal men currently receive TRT to treat their condition. Significant effort may be necessary to educate physicians, particularly primary care physicians, regarding the benefits of TRT for hypogonadal men. If TRT does not gain wider acceptance among physicians for the treatment of hypogonadism, the growth of TESTIM sales could be adversely affected.

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

We do not have the internal capability to manufacture pharmaceutical products. Under our agreement with LG Life Sciences, LG Life Sciences manufactures bulk quantities of the active pharmaceutical ingredient of FACTIVE, and we use Patheon to produce the finished FACTIVE tablets. The co-promotion agreement for TESTIM gel provides that Auxilium is responsible for the manufacture and distribution of TESTIM gel. TESTIM gel is currently manufactured for Auxilium by DPT Laboratories. Although the LG Life Sciences and DPT Laboratories 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 our products.

Auxilium's contract with DPT Laboratories to manufacture TESTIM gel expires on December 31, 2010. Although Auxilium is currently in the process of qualifying a back-up supplier to manufacture TESTIM gel, there is currently no alternative manufacturer of TESTIM gel. If there is significant delay in qualifying this back-up supplier, there could be future supply shortages of TESTIM gel. Auxilium also relies on third party suppliers for their supply of testosterone and pentadecalactone, or CPD, two key ingredients of TESTIM gel. Testosterone is available to Auxilium from only two sources. Auxilium relies exclusively on one outside source for their supply of CPD. Auxilium does not have any agreements with these suppliers regarding these key ingredients. If either of the two sources that produce testosterone stops manufacturing it, or if Auxilium is unable to procure testosterone on commercially favorable terms, Auxilium may be unable to continue to produce TESTIM on commercially viable terms, if at all. In addition, if Auxilium's third-party source of CPD stops manufacturing pharmaceutical grade CPD, or does not make CPD available to Auxilium on commercially favorable terms, Auxilium may be unable to continue to produce TESTIM on commercially viable terms, if at all. Furthermore, the limited number of suppliers of testosterone and CPD may provide such companies with greater opportunity to raise their prices. Any increase in price for testosterone or CPD may reduce the gross margins on sales of TESTIM gel.

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Pursuant to our recent acquisition from Vicuron of worldwide rights to Ramoplanin, we assumed all responsibility for manufacture of Ramoplanin and are currently in discussions with potential third-party manufacturers for Ramoplanin in order to secure long term product supply. If there is a significant delay in securing a qualified supplier on commercially favorable terms or a delay in the technology transfer from Vicuron, we could experience a supply shortage of Ramoplanin bulk drug, affecting our ability to complete the anticipated Phase III clinical program and/or begin commercialization of Ramoplanin.

We cannot be certain that LG Life Sciences, DPT Laboratories, Patheon or future manufacturers will be able to deliver commercial quantities of product or that such deliveries will be made on a timely basis. The only source of supply for FACTIVE bulk drug substance is LG Life Sciences facility in South Korea, and Patheon is currently our only source of finished FACTIVE tablets. DPT Laboratories is currently the only qualified manufacturer of TESTIM gel. If these facilities are damaged or otherwise unavailable, we could incur substantial costs and delay in the commercialization of our products. Depending upon our discussions regarding a long term source supplier 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 and TESTIM.**

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. We have an exclusive arrangement with Integrated Commercial Solutions, Inc. (ICS) to perform such supply chain manufacturing services for a three-year period. Under our agreement with Auxilium, Auxilium provides all supply chain services for TESTIM gel.

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

### **Wholesalers, pharmacies and hospitals may not maintain adequate distribution for our products.**

We sell FACTIVE to wholesale drug distributors who generally sell products to retail pharmacies and other institutional customers. We do not promote FACTIVE to these wholesalers, and they do not determine FACTIVE prescription demand. However, approximately 81% of our product shipments during 2005 were to only two wholesalers. Our ability to commercialize FACTIVE tablets will depend, in part, on the extent to which we maintain adequate distribution of FACTIVE tablets via wholesalers, pharmacies and hospitals, as well as other customers. Although a majority of the larger wholesalers and retailers distribute and stock FACTIVE tablets, they may be reluctant to do so in the future if demand is not established. Further, it is possible that wholesalers could decide to change their policies or fees, or both, at some time in the future. This could result in their refusal to distribute smaller volume products, or cause higher product distribution costs, lower margins or the need to

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find alternative methods of distributing products. Such alternative methods may not exist or may not be economically viable. If we do not maintain adequate distribution of FACTIVE tablets, the commercialization of FACTIVE and our anticipated revenues and results of operations could be adversely affected.

**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 support the development and commercialization of our products do not fulfill their obligations.**

In addition to using third parties to fulfill our manufacturing, distribution and supply chain services, our development and commercialization strategy entails entering into arrangements with corporate collaborators, contract research organizations, licensors, licensees and others to conduct development work, manage our clinical trials 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. For instance, we recently entered into a sublicense arrangement with Pfizer, S.A. de C.V. (Pfizer Mexico), whereby Pfizer Mexico will commercialize FACTIVE tablets in Mexico in exchange for which Pfizer Mexico will make to Oscient an up-front payment, and pay milestones upon obtaining certain regulatory approvals and sales goals as well as royalties on future sales.

We may not be able to maintain our existing arrangements with respect to the commercialization of our existing products, FACTIVE and TESTIM, 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 our current products, Ramoplanin or any additional products we may acquire on terms which we deem favorable, our results of operations would be materially adversely affected.

Third parties may not perform their obligations as expected. The amount and timing of resources that third parties devote to developing and commercializing our products are not within our control. Furthermore, our interests may differ from those of third parties that 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 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, TESTIM, 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.**

The Phase II trial for our product candidate, Ramoplanin, to assess the safety and efficacy of treating *Clostridium difficile*-associated disease, or CDAD, was completed in 2004. The Phase III program will be ready for initiation subject to planning and implementing a clinical trial development plan with our third-party contractor and securing additional batches of the Ramoplanin drug substance from a long term bulk drug



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supplier. Prior clinical and preclinical trials for Ramoplanin were conducted by Vicuron and its licensees, from whom we acquired rights to Ramoplanin. We may not be able to complete future 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.

We are currently conducting a Phase IV post-approval clinical trial relating to FACTIVE tablets in compliance with FDA requirements pursuant to the product's approval. Further, depending upon our discussions with the FDA regarding the ABS indication, we may need to conduct additional trials. Such trials would entail significant time and expense and the FDA has indicated doubt as to the likelihood of their success. Additionally, clinical trials may be necessary to gain approval to market the product for the treatment of other indications.

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 available to enroll in our trials;

compliance of patients and investigators with the protocol and applicable regulations;

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.

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



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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 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, develop and commercialize 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. The acquisition of rights to additional products would likely require us to make significant upfront cash payments which could adversely affect our liquidity and/or accelerate our need to raise additional capital.

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, 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.

**Results related to post-marketing studies could restrict our ability to commercialize FACTIVE tablets.**

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 post-marketing study commitment, that we conduct 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 includes 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 measures of 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 tablets, the FDA has also required us to perform a utilization study to obtain data on the prescribing patterns and use of FACTIVE tablets for the first three years after initial marketing in the U.S. As part of this requirement, we furnish interim reports to the FDA annually 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 utilization study that we are required to provide to the FDA, as well as other safety information arising out of post-marketing safety surveillance, could restrict our ability to commercialize FACTIVE tablets.

**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 69 issued U.S. patents, approximately 81 pending U.S. patent applications, 156 issued foreign patents and approximately 193 pending foreign patent applications. These patents and patent applications primarily relate to (1) the chemical composition, use, and method of manufacturing FACTIVE, (2) metalloenzyme inhibitors, their uses, their targets, (3) anti-infective compounds and their uses, and (4) the field of human and pathogen genetics. 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;



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U.S. Patent No. 5,776,944 granted July 7, 1998, 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. 5,869,670 granted February 9, 1999, relating to 7-(4-aminomethyl-3-methyloxyiminopyrrolidin-1-yl)-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1, 8-naphthyridine-3-carboxylic acid; licensed from LG Life Sciences; expiring June 15, 2015;

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

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

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

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

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

U.S. Patent No. 6,723,734 granted April 20, 2004, relating to the salt of naphthyridine 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 18 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 its 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 a patent term extension application covering the regulatory review process for one of the principal patents, U.S. Patent 5,776,944, expiring in 2015. If granted, this extension 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



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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.

The patents to Ramoplanin, which we recently acquired from Pfizer Inc., 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 years of data exclusivity under the Hatch-Waxman Act in the U.S. and the ten years of market exclusivity in Europe available through the European Commission.

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 we have exclusive rights may not result in issued patents, may result in issued patents with narrower claims than anticipated 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;

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 rely on Auxilium's license of Bentley Pharmaceuticals' intellectual property which provides limited patent protection for TESTIM.**

Currently, TESTIM gel is not covered by composition of matter patents. Testosterone, the active ingredient in TESTIM gel, is off-patent and is included in competing testosterone replacement therapy products. The U.S. patent that Auxilium licenses from Bentley Pharmaceuticals relates to a key component of the formulation of TESTIM gel and expires in June 2008. Bentley has filed a new patent application relating to the formulation in the U.S. which, if issued, could provide additional patent protection for TESTIM gel. Moreover, patent prosecution, maintenance and enforcement of the Bentley patent portfolio as it relates to TESTIM gel is controlled by Auxilium. Accordingly, we may be unable to exercise the same degree of control over this intellectual property as we would over our internally developed intellectual property or intellectual property which we directly license. Without additional patent protection, generic competition of TESTIM gel could adversely affect our sales. Furthermore, Auxilium's failure to perform under its license arrangement with Bentley could result in the termination of the license and our ability to market TESTIM gel.

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

The intellectual property rights of biopharmaceutical 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.





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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.

### **Our proprietary position may depend on our ability to protect our proprietary confidential information and trade secrets.**

We rely upon certain proprietary confidential information, 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 proprietary confidential information and trade secrets will not otherwise become known or be independently discovered by competitors.

### **We will bear substantial responsibilities under our license agreement for FACTIVE, our co-promotion agreement for TESTIM and our sublicense agreement to Pfizer, S.A. de C.V., and there can be no assurance that we will successfully fulfill our responsibilities.**

#### *FACTIVE*

We have an 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. 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

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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.

Further, we recently entered into a Sublicensing and Distribution Agreement with Pfizer, S.A. de C.V. (Pfizer Mexico) whereby we sublicensed our rights to commercialize FACTIVE tablets in Mexico to Pfizer Mexico. Under this agreement, we are obligated to exclusively supply all active pharmaceutical ingredient for FACTIVE required by Pfizer Mexico in Mexico. We believe that, together with our manufacturing partners, we will be able to meet such supply and other obligations under the sublicense agreement but can make no assurances to that we will be able to remain in compliance with such responsibilities.

*Auxilium*

On April 11, 2005, we entered into an agreement with Auxilium granting us the exclusive right to co-promote TESTIM gel to primary care physicians in the U.S. Under this agreement we are obligated to share TESTIM promotional expenses to this audience equally with Auxilium. The agreement also requires minimum levels of annual physician detailing which, if not met, would allow Auxilium to terminate the agreement. The initial term of the agreement ends on April 30, 2007. We may extend the agreement for two consecutive two-year periods provided that certain milestones related to physician detailing, market share and gross sales have been met by us for each extension period. We believe that we are currently in compliance with our obligations under the Auxilium agreement, but there can be no assurance that we will be able to remain in compliance or that we will be able to meet the milestones required for extension of the agreement.

**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 Dominick Colangelo, Esq., Executive Vice President, Corporate Development and Operations. The term of each employment agreement continues until it is terminated by the officer or us.

Our future success is dependent upon our ability to attract and retain additional qualified sales and marketing, clinical development, scientific and managerial personnel. The launch of the commercial sale of FACTIVE tablets during the second half of 2004 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

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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.

**Changes in the expensing of stock-based compensation will result in unfavorable accounting charges and may require us to change our compensation practices. Any change in our compensation practices may adversely affect our ability to attract and retain qualified scientific, technical and business personnel.**

We rely heavily on stock options to compensate existing employees and attract new employees. As a result of new accounting rules implemented by the Financial Accounting Standards Board, as of January 1, 2006, we were required to record expense for the fair value of stock options and purchase rights under our employee stock purchase plan, thereby increasing our operating expenses and reported losses. Although we intend to continue to include various forms of equity in our compensation plans, if the extent to which we use forms of equity in our plans is reduced due to the negative effects on earnings, it may be difficult for us to attract and retain qualified scientific, technical and business personnel.

**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 included all of the members of the European Union on the date of the original agreement to license FACTIVE. However, in 2004, a number of additional European countries in which we do not have rights to market FACTIVE were 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, 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 or obtain regulatory approval in foreign jurisdictions will prevent us from marketing FACTIVE abroad.**

We recently entered into a Sublicensing and Distribution Agreement with Pfizer, S.A. de C.V. (Pfizer Mexico) whereby we sublicensed our rights to sell FACTIVE tablets in Mexico to Pfizer Mexico. We intend to further market FACTIVE through distribution partners in most, if not all, of the other international markets for which we have a license to market the product. This will include the European Union and Canada. We may not be able to secure distribution partners at all, or those that we do secure, including our relationship with Pfizer Mexico, may not be successful in obtaining regulatory approval for, 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.

Further, in order to market FACTIVE in the European Union, Mexico 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. For instance, our predecessor's original regulatory filing in the UK was rejected. 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.

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### **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, 2005, we had approximately \$178,403,000 indebtedness outstanding (including accrued interest and 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.

### **We will rely upon alliance partners from our previous genomics-based research and alliance business as a means of developing and commercializing related 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. Prior to 2004, we received a majority 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 our 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.

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**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, TESTIM gel, 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 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, TESTIM gel, 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, TESTIM gel, 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 our products.

**Wholesalers, pharmacies and hospitals may not provide adequate distribution for our products.**

Our ability to commercialize our products will depend, in part, on the extent to which we obtain adequate distribution of our products via wholesalers, pharmacies and hospitals, 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 commercialization of FACTIVE and TESTIM 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.

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**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 report, as well as other factors, including:

our ability to successfully commercialize FACTIVE tablets and TESTIM;

the revenues that we may derive from the sale of FACTIVE tablets and TESTIM, 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;

sales of shares of our common stock in the public market; and

comments by securities analysts, or our failure to meet market expectations.

Over the two-year period ending December 31, 2005 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 \$1.60. 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 of 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 and TESTIM;

the level of acceptance by physicians and third party payors of FACTIVE and TESTIM;

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



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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.

### **Item 1B. Unresolved Staff Comments**

None.

### **Item 2. Properties**

Our executive offices are located at 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 our former executive offices located at 100 Beaver Street, Waltham, Massachusetts, and our lease expires on November 15, 2006. During 2005, we incurred aggregate rental costs, excluding maintenance and utilities, for our Waltham facilities of approximately \$1,774,000. We have subleased approximately 47,000 square feet at our former Beaver Street facility as of December 31, 2005. In 2005, we received approximately \$1,759,000 in sublease income.

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 remaining average yearly base rent for the west coast facility is approximately \$4,076,000. The lease for this facility expires on February 28, 2011 and we have sub-leased to third parties approximately 61,300 square feet of the facility through April 30, 2007. In 2005, we received approximately \$1,813,000 in sublease income from the west coast subleases.

### **Item 3. Legal Proceedings**

From time to time we are involved in legal actions in the normal course of business, some of which seek monetary damages, including claims for punitive damages. These actions, when finally concluded and determined, will not, in our opinion, have a material adverse effect on our financial position, results of operations or cash flows.

We believe that we have obtained adequate insurance or, where appropriate, have established adequate reserves in connection with these legal proceedings.

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

None.

**Table of Contents****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 2004 and 2005 as reported by the National Association of Securities Dealers Quotation System.

	2005		2004	
	High	Low	High	Low
First Quarter	\$ 3.82	\$ 2.05	\$ 7.18	\$ 3.05
Second Quarter	2.90	1.61	6.85	4.36
Third Quarter	3.04	1.96	5.29	3.25
Fourth Quarter	2.45	1.53	3.92	2.71

As of February 28, 2006, there were approximately 1,148 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 our company, our capital requirements and general business conditions.

In the third quarter of 2005, we filed a shelf registration statement with the Securities and Exchange Commission that allows us to sell up to \$100,000,000 of our common stock in one or more separate offerings in amounts, at prices and on terms to be determined at the time of such offer or offerings.

**Equity Compensation Plan Information**

Plan category	(a) Number of securities to be issued upon exercise of outstanding options	(b) Weighted-average exercise price of outstanding options	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	8,861,971	\$ 4.06	1,950,257

**Recent Sales of Unregistered Securities**

None.

**Company Purchases of Equity Securities**

We did not make any purchases of our common stock during the year ended December 31, 2005.

**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.

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We derived the statement of operations data for the years ended December 31, 2005, 2004 and 2003 and the balance sheet data as of December 31, 2005 and 2004 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, 2002 and 2001 and the balance sheet data as of December 31, 2003, 2002 and 2001 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 (in thousands, except per share data).

	2005	For the Year Ended December 31,			2001
		2004	2003	2002	
<b>Revenues:</b>					
Product sales	\$ 20,458	\$ 4,067	\$	\$	\$
Co-promotion	2,954				
Biopharmaceutical	197	2,546	7,009	7,716	18,438
<b>Total revenues (1)</b>	<b>23,609</b>	<b>6,613</b>	<b>7,009</b>	<b>7,716</b>	<b>18,438</b>
Costs of product sales and operating expenses	112,281	97,229	39,943	41,460	32,825
<b>Loss from operations</b>	<b>(88,672)</b>	<b>(90,616)</b>	<b>(32,934)</b>	<b>(33,744)</b>	<b>(14,387)</b>
Income (loss) from discontinued operations	35	208	(401)	(157)	1,150
<b>Net loss</b>	<b>\$ (88,593)</b>	<b>\$ (93,271)</b>	<b>\$ (29,789)</b>	<b>\$ (34,017)</b>	<b>\$ (10,090)</b>
Net loss per common share basic and diluted	(1.16)	(1.33)	(1.13)	(1.48)	(0.45)
Weighted average basic and diluted common shares outstanding	76,549	70,350	26,290	22,921	22,572

(1) Does not include revenue from discontinued operations related to our genomics business.

	As of December 31,				
	2005	2004	2003	2002	2001
Cash and cash equivalents, restricted cash, and long and short-term marketable securities	\$ 80,044	\$ 176,628	\$ 28,665	\$ 50,866	\$ 67,341
Working capital	77,750	156,021	18,897	36,511	44,156
<b>Total assets</b>	<b>241,095</b>	<b>340,560</b>	<b>40,516</b>	<b>65,845</b>	<b>82,740</b>
Long-term liabilities	191,289	193,397	292	15,654	2,061
Shareholders' equity	28,101	114,400	29,940	35,417	66,732

**Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations****FORWARD-LOOKING STATEMENTS**

Certain statements contained herein related to future operating losses and our potential for profitability, the sufficiency of our cash resources, future revenues and sales of FACTIVE® and TESTIM®, our discount and rebate programs for FACTIVE, gross margin in future periods, our ability to obtain approval from the FDA for a five-day course of therapy for CAP, our discussions with the FDA regarding its rejection of our ABS filing, our ability to secure a long term source of bulk drug supply for Ramoplanin as well as other statements related to the progress and timing of product development, present or future licensing, collaborative or financing arrangements or that otherwise relate to future periods, are 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, expect and similar expressions are intended to identify

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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 are included under the heading **Risk Factors** in this Form 10-K. We encourage you to read these risks 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 commercial-stage biopharmaceutical company committed to the clinical development and commercialization of new therapeutics to serve unmet medical needs. We currently promote two products in the U.S. pharmaceutical market. Our lead product is the fluoroquinolone antibiotic FACTIVE® (gemifloxacin mesylate) tablets, indicated 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 and FACTIVE is currently promoted nationally by a sales team comprised of approximately 300 representatives. We also co-promote Auxilium Pharmaceuticals, Inc.'s marketed product, TESTIM gel, a topical 1% testosterone gel indicated for the treatment of male hypogonadism. Additionally, we are developing a novel antibiotic candidate, Ramoplanin, for the treatment of *Clostridium difficile*-associated disease.

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.

We have incurred significant operating losses since our inception. As of December 31, 2005, we had an accumulated deficit of approximately \$337,428,000. We expect to incur additional operating losses over the next several years due to the implementation of manufacturing, distribution, marketing and sales capabilities, as well as continued research and development efforts, preclinical testing and clinical trials.

## **FACTIVE**

Our lead product is FACTIVE tablets, indicated for the treatment of community-acquired pneumonia of mild to moderate severity, or CAP, and acute bacterial exacerbations of chronic bronchitis, or AECB. The product was approved for sale in the United States in April 2003 for such indications.

In October 2002, Genesoft, now a subsidiary of ours, entered into a license and option agreement with LG Life Sciences to develop and commercialize gemifloxacin, a novel fluoroquinolone 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. This agreement was subsequently assigned to us. 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 for composition of matter expires in 2018.

We began selling FACTIVE tablets in September 2004 with an initial sales force of 100 representatives and, as of December 2005, had an approximately 250 person sales force. Additionally, in October 2005, we supplemented the Oscient sales force with approximately 50 contract sales representatives, hired by Innovex, the contract sales arm of Quintiles Transnational Corp. These additional sales representatives provide double coverage in 50 high potential territories to grow the FACTIVE physician prescribing base.

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We are also seeking to expand the commercial opportunities for FACTIVE through additional development and clinical study plans for the product. We have completed a clinical trial to demonstrate that a five-day course of FACTIVE for the treatment of mild to moderate CAP is as effective as the currently approved seven-day course of treatment. The FDA has recently accepted for filing our supplemental sNDA seeking marketing approval for the use of FACTIVE for the five-day treatment of CAP. The FDA granted a standard ten-month review period for the five-day CAP sNDA and is expected to act on the filing by the end of September 2006. The acceptance of the CAP sNDA filing does not assure approval.

As part of the FACTIVE development program, several studies relating to acute bacterial sinusitis, or ABS, were completed; however, the FDA has refused to accept the sNDA filing for the five-day treatment of ABS. In its refusal to accept the sNDA filing for ABS, the FDA indicated that FACTIVE did not exhibit an acceptable risk versus benefit profile for the ABS indication. In addition, the FDA expressed the opinion that demonstrating an acceptable risk versus benefit profile for FACTIVE in ABS was not feasible, given the FDA's view of the potential risk of rash in those patients. Although we intend to continue our discussions with the FDA regarding the ABS indication, we cannot guarantee that the ABS indication will ever be approved by the FDA.

In addition, we plan to develop an intravenous formulation of gemifloxacin. Due to the risks and uncertainties inherent in clinical trials, we cannot predict if final results related to these efforts will be successful or when material cash flows from these programs will commence.

## **Co-Promotion of TESTIM**

On April 11, 2005, we entered into a co-promotion agreement with Auxilium Pharmaceuticals, Inc. under which we and Auxilium will co-promote in the United States Auxilium's marketed product, TESTIM gel, a topical 1% testosterone gel indicated for the treatment of male hypogonadism. Pursuant to the agreement, we have the exclusive right to promote TESTIM gel jointly with Auxilium to primary care physicians. The initial term of the agreement ends on April 30, 2007. We may extend the agreement for two consecutive two-year periods provided that we have met certain milestones for each extension related to physician detailing, market share and gross sales. If these milestones are met and we do not elect to terminate the co-promotion agreement, the first extension period will end on December 31, 2008 and the second extension period will end on April 30, 2011.

Both organizations have established and continue to develop a promotion plan which sets forth the responsibilities of both parties with respect to the marketing and promotion of TESTIM gel in the U.S. primary care physician market. We are obligated to share TESTIM promotional expenses to this physician market equally with Auxilium. Each party will be responsible for the costs associated with its own sales force. In addition, Auxilium is obligated to pay us a co-promotion fee based on a specified percentage of the gross profit from TESTIM sales attributable to primary care physicians in the U.S. that exceeds a specified sales threshold. The specific percentage is based upon TESTIM sales levels attributable to primary care physicians and the marketing expenses incurred by us in connection with the promotion of TESTIM gel under the co-promotion agreement. The co-promotion agreement can be terminated by either party upon the occurrence of certain termination events, including approval and sale of a generic form of TESTIM gel in the United States, in which case Auxilium is obligated to pay to us a specified percentage of the profits for product sales for the following two years. Also, we have been granted the exclusive option to co-promote any future Auxilium product candidate that treats male hypogonadism and contains testosterone as the active ingredient. The terms and conditions of such future agreement would be negotiated in good faith by the parties at the time the option is exercised.

## **Ramoplanin**

We are developing a novel investigational antibiotic candidate, Ramoplanin, which is currently in development for the treatment of *Clostridium difficile*-associated disease, or CDAD. In October 2001, we in-licensed Ramoplanin from Vicuron Pharmaceuticals Inc. (Vicuron), now a wholly-owned subsidiary of Pfizer Inc., and on February 3, 2006, acquired worldwide rights from Vicuron, assuming full control of Ramoplanin manufacturing, development and commercialization.

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We recently agreed with the FDA to a Special Protocol Assessment (SPA) regarding the specific components of the Phase III program that, if completed successfully, would support regulatory approval for the indication. According to the agreement reached with the FDA, the required clinical development program will be comprised of two pivotal Phase III trials. The two non-inferiority studies will enroll, in each trial, approximately 490 patients diagnosed with CDAD, from centers in the United States, Canada and other parts of the world. Each patient will be randomly assigned to one of two treatment arms, in a double-blind fashion: Ramoplanin 200 mg twice daily or vancomycin 125 mg four times daily for ten days. The primary endpoint will be the response rate at end of therapy. Once we finalize planning and implementing a clinical trial development plan with our third-party contractor and secure a long-term source supplier, we would be ready to initiate the Phase III program.

### **Other Alliances and Research Programs**

#### *Genomic Alliances and Services*

Previously, we received payments from our product discovery alliances based on license fees, contract research and milestone payments during the term of our alliances. Our alliances could 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 partners to conduct preclinical tests and clinical trials, obtain regulatory clearances, manufacture, sell and distribute the product. Accordingly, we do not expect to receive significant milestone payments and royalties based upon product revenues for many years, if at all. We expect the majority of our revenue in the future to be derived from the sale of current and future products.

In the past, we have also received revenues from our genomics services business from selling, as a contract service business, high quality genomic sequencing information to our customers. As part of our continued evolution into a 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). We retain rights to our PathoGenome Database product, including all associated intellectual property, subscriptions and royalty rights on products developed by subscribers. As part of the agreement with Agencourt, we transferred our sequencing operations, including certain equipment and personnel, to Agencourt for the following consideration:

an up-front cash payment of \$200,000;

cash payments over a two year period ending in March 2005 totaling approximately \$784,000 pursuant to a right to receive a percentage of revenues from our former commercial and government customers; and

500,000 shares of Agencourt's common stock.

As a result of the acquisition of Agencourt by Beckman Coulter, we received (i) a payment of approximately \$2,245,000 during the quarter ended June 30, 2005, in exchange for the shares of Agencourt we held, (ii) a payment of approximately \$143,000 during the quarter ended September 30, 2005 due to a post-closing merger adjustment, and (iii) the right to receive additional consideration if certain milestones are achieved by Agencourt over the next three years.

#### *Internally Funded Early-Stage Target Research Program*

As part of our strategic decision to concentrate on development and commercialization of our pharmaceutical products, we adopted a plan in 2003 to substantially reduce our research effort in internally funded early-stage target discovery programs. Under this plan, we eliminated 44 full-time positions and paid out \$609,000 related to severance costs against the restructuring liability in 2004. This charge includes associated

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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.

On May 16, 2005 we entered into a License and Contribution Agreement with MaxThera, Inc., whereby we granted an exclusive license to certain patent rights relating to certain of our legacy anti-infective technology. Title to these patent rights will vest in MaxThera upon meeting certain financial milestones. In consideration of the license and upon transfer of title to MaxThera, we will receive shares of MaxThera's common stock as well as a right to royalty payments if any products covered by the patent rights are commercialized.

On May 31, 2005 we entered into a License and Sale Agreement with Azee, Inc., whereby we granted an exclusive license to certain patent rights relating to Genesoft's small molecule anti-genomic therapeutics legacy technology. Title to these patent rights will vest in Azee upon Azee meeting certain financial milestones. In consideration of the license, we received shares of Azee's common stock and are entitled to royalty payments if any products covered by the patent rights are commercialized. Upon transfer of title to the patents to Azee, we will receive additional shares of Azee's common stock.

As a combined category, these research efforts represented 0% and 9% of total research and development expenses for the fiscal years ended December 31, 2005 and 2004, respectively.

## **MAJOR RESEARCH AND DEVELOPMENT PROJECTS**

Research and development expenditures totaled approximately \$14,432,000, \$29,557,000 and \$22,314,000 for the years ended December 31, 2005, 2004, and 2003, respectively.

### **FACTIVE (gemifloxacin mesylate) Tablets**

Expenses for ongoing clinical trials and other development activities for the FACTIVE product totaled approximately \$13,042,000 in 2005.

As a condition to the approval to sell FACTIVE tablets, the FDA has required, as a post-marketing study commitment, that we conduct a prospective, randomized study comparing FACTIVE tablets (5,000 patients) to an active comparator (2,500 patients) in patients with acute bacterial exacerbations of chronic bronchitis and community-acquired pneumonia of mild to moderate severity. This study will include patients of different ethnicities to gain safety information in populations not substantially represented in the existing clinical trial program. Patient enrollment for this Phase IV trial, with approval from the FDA, commenced patient enrollment during the fall of 2004 and is scheduled to be completed within three to four years. Although we cannot predict with certainty the costs necessary to complete this study, we currently estimate it will cost between \$7-8 million of additional spending to complete the study.

Additionally, in April of 2005, we completed a Phase III trial examining the potential use of FACTIVE tablets for the five-day treatment of mild to moderate community-acquired pneumonia. Based on the results of this study, in October 2005 we submitted a supplemental New Drug Application with the FDA for approval to promote the five-day treatment of FACTIVE tablets for this indication. In January 2006, the FDA accepted our submission for filing. We expect the FDA to act on our application by the end of September 2006. There is no assurance that the FDA will approve our application.

### **Ramoplanin**

Clinical trials and other development activities for Ramoplanin constituted our most significant research and development projects in 2003 and 2004, but were only a small part of expenditures in 2005. During 2005, we focused on reaching agreement with the FDA for a Phase III program pursuant to a Special Protocol Assessment

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(SPA). We are in the process of finalizing plans for the required clinical trials. Once our initial planning is complete, the development of Ramoplanin, including cost and timing, will remain subject to numerous factors beyond our control, such as identifying centers and physicians to conduct the clinical trials, the pace of enrollment in clinical trials, possible regulatory delays of clinical trials and the strength of the data produced by a given trial. As a result of these factors, we are unable to determine the estimated completion date or the estimated cost to complete the Ramoplanin trial.

### **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. The costs for internally funded research in 2005 were minimal in comparison to our total expenditures.

With respect to our earlier stage programs, we do not track total actual costs or estimated costs to completion for each of our preclinical projects. We have not disclosed the nature, timing and cost of the efforts necessary to complete our other projects or the anticipated completion dates, because these items are not known or estimable by us. For instance, before we could even begin clinical trials for any of these programs, we would have to identify lead compounds, complete preclinical safety testing of these compounds and file an investigational new drug (IND) with the FDA. Given the risk of scientific failure inherent in early stage discovery programs, we cannot predict the estimated completion date or estimated cost to complete any of our research and development projects and given the uncertainties related to development, we are currently unable to reliably estimate, when, if ever, our product candidates will generate revenue and cash flows.

### **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 2 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**

Our principal source of revenue is the sale of FACTIVE tablets, which began shipping in the third quarter of 2004. In the second quarter of 2005, we began recognizing co-promotion revenue in connection with our agreement with Auxilium. Other historical sources of revenue include biopharmaceutical alliances and royalties from the divested genomic services business. In future periods, we expect our revenues derived from biopharmaceutical alliances will continue to decrease, however product revenues and co-promotion revenues will continue to increase based on anticipated increased volume of prescriptions of FACTIVE tablets and TESTIM testosterone gel.

We expect demand for FACTIVE to be higher between November 1 and March 31 as the incidence of respiratory tract infections, including CAP and AECB, tend to increase during the winter months. As a result, we



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expect our sales of FACTIVE to be higher during this season. In addition, fluctuations in the severity of the annual respiratory tract infection season may cause our product sales to vary from year to year. Due to these seasonal fluctuations in demand, our results in any particular quarter may not be indicative of the results for any other quarter or for the entire year.

### **Product Sales**

We follow the provisions of Staff Accounting Bulletin No. 104, Revenue Recognition (a replacement of SAB 101) and 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 collectability of the related receivable is reasonably assured. All revenues from product sales are recorded net of applicable allowances for sales returns, rebates, special promotional programs, and discounts. For arrangements where the risk of loss has not passed to wholesalers or pharmacies, we defer the recognition of revenue by recording deferred revenue until such time as risk of loss has passed. Also, the cost of FACTIVE associated with amounts recorded as deferred revenue is recorded in inventory until such time as risk of loss has passed. As of December 31, 2005 and 2004, the balance of deferred revenue was \$0 and \$1,302,000, respectively.

### **Co-Promotion Revenue**

Amounts earned under our co-promotion agreement with Auxilium from the sale of TESTIM gel, a product developed by Auxilium, is classified as co-promotion revenue in our statements of operations included in this report. Auxilium is obligated to pay us a co-promotion fee based on a specified percentage of the gross profit from TESTIM sales attributable to primary care physicians in the U.S. that exceeds a specified sales threshold. The specific percentage is based upon TESTIM sales levels attributable to primary care physicians and the marketing expenses incurred by us in connection with the promotion of TESTIM gel under the co-promotion agreement. Such co-promotion revenue is earned when TESTIM units are dispensed through patient prescriptions. There is no cost of goods sold associated with co-promotion revenue, and the selling and marketing expenses incurred with respect to the co-promotion arrangement are included in selling and marketing expenses.

### **Biopharmaceutical Revenue**

Prior to the merger with Genesoft, we pursued biopharmaceutical revenues through alliance partnerships with pharmaceutical companies and through government grants. We also maintained a genomics services business. We have now shifted our focus to the development and commercialization of pharmaceutical products. The declining revenues and associated expenses for the genomics services business have been classified as discontinued operations in the accompanying consolidated financial statements.

Biopharmaceutical revenues have consisted of government research grants and license fees, contract research, and milestone payments from alliances with pharmaceutical companies. Genomics services revenues have consisted of government sequencing grants, fees and royalties received from custom gene sequencing, and analysis services.

### **Sales Rebates, Discounts and Incentives**

Our product sales are made to pharmaceutical wholesalers for further distribution through pharmacies to the ultimate consumers of the product. When we deliver our product, we reduce the amount of gross revenue recognized from such product sales based primarily on estimates of three categories of discounts and allowances—product returns, sales discounts and allowances and special promotional programs that suggest that all or part of the revenue should not be recognized at the time of the delivery.

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### *Product Returns*

Factors that are considered in our estimate of future product returns include an analysis of the amount of product in the wholesaler and pharmacy channel, review of consumer consumption data as reported by external information management companies, return rates for similar competitive antibiotic products that have a similar shelf life and are sold in the same distribution channel, the remaining time to expiration of our product, and our forecast of future sales of our product. Consistent with industry practice, we offer contractual return rights that allow our customers to return product within six months prior to and six months subsequent to the expiration date of our product. Our product has a 36-month expiration period from the date of manufacturing into a tablet. Based on the contractual terms of the product return rights, the product in the channel is eligible for return after March 31, 2006. At December 31, 2005 and 2004, our product return reserve was approximately \$720,000 and \$242,000, respectively. This reserve is evaluated on a quarterly basis, assessing each of the factors described above, and adjusted accordingly. Based on the factors noted above, we believe our estimate of product returns is reasonable, and changes, if any, from this estimate would not have a material impact to our financial statements.

### *Cash Discounts*

Our standard invoice includes a contractual cash 2% discount, net 30 days terms. Based on historical experience, we estimate that most of our customers deduct a 2% discount from their balance. The cash discount reserve is presented as an allowance against trade receivables. As of December 31, 2005 and 2004, the balance for cash discounts was approximately \$50,000 and \$79,000, respectively.

### *Rebates*

The liability for managed care rebates is based upon historical and current rebate redemption and utilization rates contractually submitted by each state. As of December 31, 2005 and 2004 the balance for managed care rebates was approximately \$381,000 and \$379,000, respectively. Considering the estimates made by us, as well as estimates prepared by third party utilization reports that are necessary in evaluating the required liability balance, we believe our estimates are reasonable, and changes, if any, from those estimates would not be material to the financial statements. As of December 31, 2005, there have been no material changes to our estimates in the periods presented.

### *Special Promotional Programs*

We have offered certain promotional incentives to date to our customers and may continue this practice in the future such as sample cards to end consumers, certain product incentives to pharmacy customers, and other sales stocking allowances. Examples of programs utilized to date follow:

#### *Voucher Rebate Programs*

During the first quarter of 2005, we initiated a voucher rebate program which offered a mail-in rebate to patients who received a FACTIVE prescription. We have accounted for this program in accordance with Emerging Issues Task Force No. 01-09, *Accounting for Consideration Given by a Vendor to a Customer* (EITF No. 01-09). We developed a reasonable estimate of the liability for this program based upon historical redemption rates for completed programs by utilizing a third party processing company. The program was completed by December 31, 2005.

During the fourth quarter of 2005, we initiated another voucher rebate program whereby we offered mail-in rebates to retail consumers. We have accounted for this program in accordance with EITF No. 01-09. The liability we recorded for this voucher rebate program is based upon the historical rebate redemption rates for the similar completed program that we commenced in the first quarter of 2005. As of December 31, 2005, the balance of the liability for this voucher program was approximately \$93,000. The program will expire on April 30, 2006 and the balance will be adjusted for the actual redemption rate.

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### *Sample Card Rebate Program*

During the fourth quarter of 2004, we initiated a sample card program whereby we offered an incentive to patients in the form of a free full-course sample card for FACTIVE. We have accounted for this program in accordance with EITF No. 01-09. We did not have sufficient history with this type of incentive program in order to develop a reasonable and reliable estimate of the amount of expected reimbursement claims. As a result, in accordance with Issue 4 of EITF No. 01-09, we recorded the maximum reserve (100% redemption) for reimbursement claims related to sample cards distributed, which resulted in a reduction of revenues of approximately \$920,000 at December 31, 2004. During the quarter ended September 30, 2005, we adjusted the reserve based upon the completion of the program which resulted in the recognition of product revenue of approximately \$1,630,000. We may be able to consider the actual redemption rate from this program in estimating the liability for similar programs in the future.

### *Stocking Incentives*

During the third quarter of 2004, in connection with the commercial launch of FACTIVE, we offered certain product stocking incentives to a number of pharmacy customers. These incentives included products with limited guaranteed sales provisions of up to nine months from date of purchase. As a result of these provisions, title and risk of loss of these products had not passed to the customer. Accordingly, we deferred all revenue related to these products until such time as the unit was provided to a patient with a prescription. As of December 31, 2004, we had recorded deferred revenue of \$1,302,000 related to these units. The guaranteed sales provisions expired on September 30, 2005 and the remaining deferred revenue related to these units of approximately \$885,000 was recognized as revenue.

### **Clinical Trial Expense Accrual**

Our clinical development trials related to FACTIVE and Ramoplanin are primarily performed by outside parties. At the end of each accounting period, we estimate both the total cost and time period of the trials and the percent completed as of that accounting date. We also adjust these estimates when final invoices are received. For the fiscal year ended December 31, 2005, we adjusted our accrual for clinical trial expenditures to reflect our most current estimate of liabilities outstanding to outside parties. However, the possibility exists that the timing or cost of the clinical trials might be longer or shorter and cost more or less than we have estimated and that the associated financial adjustments would be reflected in future periods.

### **Inventories**

Inventory is stated at the lower of cost or market with cost determined under the average cost method. Inventory consists of FACTIVE raw material in powder form and work-in-process of approximately \$9,770,000 and \$4,373,000, and FACTIVE finished tablets of approximately \$4,417,000 and \$3,752,000, as of December 31, 2005 and 2004, respectively. On a quarterly basis, we analyze our inventory levels, and write down inventory and marketing samples that have become obsolete, have a cost basis in excess of its expected net realizable value or are in excess of expected requirements to cost of product revenues and marketing expense, respectively. Expired inventory will be disposed of and related costs will be written off. During 2005 and 2004, we recorded an inventory reserve provision of approximately \$1,078,000 and \$11,000, respectively to cost of sales related to slow moving and obsolete inventory. At December 31, 2005 and 2004, there was approximately \$2,072,000 and \$3,791,000 respectively, in FACTIVE sample product to be used for FACTIVE marketing programs, which is classified as an other current asset in the accompanying consolidated balance sheet.

### **Restructuring Charges**

During the years ended December 31, 2004 and 2003, we recorded restructuring charges of \$4,780,000 and \$5,257,000, respectively. We also recorded a facility lease liability of \$21,617,000 and severance related costs of \$1,419,000 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

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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 judgmental estimates related to these restructuring charges. For example, the consolidation of facilities required us to record a restructuring charge which was based on estimates of rental commitments for office and laboratory space being vacated and related costs, 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 in South San Francisco, California, we may be required to further revise the restructuring accrual and accrued facilities impairment charge that we have recorded as of December 31, 2005. For further discussion on our restructuring activities, see Note 4 in the Notes to Consolidated Financial Statements.

### **Long-Lived Assets**

We follow the provisions of SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets (SFAS No. 144). Under SFAS 144, long-lived assets and identifiable intangible assets with finite lives are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If indicators of impairment exist, recoverability of assets to be held and used is assessed by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. Recoverability measurement and estimating the undiscounted cash flows is done at the lowest possible level for which there are identifiable assets. If the aggregate undiscounted cash flows are less than the carrying value of the asset, then the resulting impairment charge to be recorded is calculated based on the amount by which the carrying amount of the asset exceeds its fair value. Any write-downs are recorded as permanent reductions in the carrying amount of the asset.

We also follow the provisions of SFAS No. 142, Goodwill and Other Intangible Assets, (SFAS No. 142). Under SFAS 142, goodwill and purchased intangible assets with indefinite lives are not amortized but are reviewed periodically for impairment. We perform an annual evaluation of goodwill at the end of each fiscal year to test for impairment or more frequently if events or circumstances indicate that goodwill may be impaired. Because we have a single operating segment, which is our sole reporting unit, we perform this test by comparing the fair value of the entity with our book value, including goodwill. If the fair value exceeds the book value, goodwill is not impaired. If the book value exceeds the fair value, then we would calculate the potential impairment loss by comparing the implied fair value of goodwill with the book value. If the implied fair value of goodwill is less than the book value, then an impairment charge would be recorded.

As of December 31, 2005, we do not believe that any of our long-lived assets, goodwill, and other intangible assets are impaired.

## **RESULTS OF OPERATIONS**

### **Years Ended December 31, 2005 and 2004**

#### **Revenues**

Total revenues increased significantly to \$23,609,000 for the year ended December 31, 2005 from \$6,613,000 for the year ended December 31, 2004.

Product sales increased to \$20,458,000 for the year ended December 31, 2005 from \$4,067,000 for the year ended December 31, 2004. The commercial sale of FACTIVE tablets was launched in September 2004, and thus, the 2004 year represents four months of FACTIVE revenue as opposed to a full year of revenue for 2005.

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Co-promotion revenue increased to \$2,954,000 for the year ended December 31, 2005 from \$0 for the year ended December 31, 2004 due to the introduction of co-promoting TESTIM during the second quarter of 2005.

Biopharmaceutical revenues decreased 92% to \$197,000 for the year ended December 31, 2005 from \$2,546,000 for the year ended December 31, 2004, reflecting our strategic shift to commercialization of pharmaceutical products.

Our revenue mix shifted during 2004. We expect that our revenues derived from both our biopharmaceutical alliance and genomics services will be minimal in comparison to prior years. We expect an increase in product revenues based on the sale of FACTIVE tablets and we also expect an increase in co-promotion revenues based on the sale of TESTIM due to our co-promotion agreement signed in the second quarter of 2005.

### **Costs and Expenses**

Total costs and expenses increased 15% to \$112,281,000 for the year ended December 31, 2005 from \$97,229,000 in 2004, primarily reflecting a full year of selling and marketing expense in 2005 due to the launch of FACTIVE in September 2004.

Cost of product sales increased 191% to \$9,830,000 in 2005 from \$3,381,000 in 2004. The commercial sale of FACTIVE tablets was launched in September 2004, and, thus, the current period represents a full year of sales compared to the initial product launch in the prior period. Included in the cost of product sales is \$4,766,000 and \$1,981,000 for 2005 and 2004, respectively, of amortization of intangible assets associated with FACTIVE. Our gross margin on FACTIVE for the year ended December 31, 2005 and 2004, after standard product cost and royalties, but excluding amortization of intangible assets, was 75% and 66%, respectively. Our gross product margin at December 31, 2005 and 2004 including amortization of intangible assets was 52% and 17%, respectively. The primary reason for the improved margin was due to higher sales in 2005 and also due to approximately \$800,000 of other manufacturing costs mainly related to the technology transfer to our new manufacturing site of FACTIVE tablets that was incurred in 2004.

Research and development expenses decreased 51% to \$14,432,000 in 2005 from \$29,557,000 in 2004. 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 research and development. Other research and development expenses include fees paid to consultants and outside service providers. The decrease in research and development is primarily due to a decrease of approximately \$7,849,000 relating to the termination of the Ramoplanin VRE trial in July 2004, a decrease of approximately \$3,833,000 related to internal research effort and alliances as well as a decrease of approximately \$2,879,000 in connection with the feasibility testing of FACTIVE manufacturing in a new contracted manufacturing site and a decrease in stock based compensation in the amount of \$2,902,000 due to lower amortization of deferred compensation resulting from stock options that were issued as part of the merger with GeneSoft Pharmaceuticals in 2004 and decreased expenses related to terminations of personnel following the merger. These decreases are offset by an increase of approximately \$2,338,000 in connection with the clinical trials for FACTIVE related to the five-day CAP study and the FACTIVE post-marketing study.

Selling and marketing expenses significantly increased 115% to \$74,931,000 in 2005 from \$34,826,000 in 2004. This increase was primarily due to additional sales and marketing personnel and associated hiring costs of \$24,625,000 and consulting costs of \$9,188,000, increased other marketing, advertising and promotional costs of approximately \$4,465,000 to support the launch of FACTIVE, increased costs of \$3,539,000 associated with the promotion of TESTIM which began in the second quarter of 2005, offset by decreases of approximately \$1,712,000 associated with marketing studies and other costs.

General and administrative expenses increased 1% to \$13,088,000 in 2005 from \$12,981,000 in 2004 primarily due to an increase in general and administrative payroll and related costs of approximately \$810,000 and an increase of approximately \$460,000 in other general and administrative expenses offset by a decrease in

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stock based compensation in the amount of \$1,163,000 due to lower amortization of deferred compensation resulting from stock options that were issued as part of the merger with GeneSoft Pharmaceuticals in 2004 and decreased expenses related to terminations of personnel following the merger.

As part of our merger with Genesoft, we recorded a one-time charge of approximately \$11,704,000 in 2004 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 of \$11,704,000 includes a peptide deformylase inhibitor research program (PDF) licensed from Vernalis (R & D) Limited for the treatment of infections.

Restructuring charges were \$4,780,000 in 2004, consisting of \$4,681,000 for the Beaver Street Waltham Massachusetts facility and \$99,000 for severance costs.

## **Other Income and Expense**

Interest income increased 40% to approximately \$3,400,000 in 2005 from approximately \$2,424,000 in 2004 reflecting higher yields on cash balances offset by lower overall cash balances in 2005.

Interest expense significantly increased to approximately \$8,126,000 in 2005 from approximately \$5,625,000 in 2004. In 2005, interest expense primarily consisted of approximately \$5,346,000 related to the issuance of \$153 million of senior convertible notes in the second quarter of 2004, approximately \$1,180,000 related to the issuance of \$22 million of convertible notes in connection with the Genesoft merger, \$815,000 related to amortization of deferred financing costs along with approximately \$742,000 related to non-cash interest expense related to the facility lease liability.

We recorded a gain on the sale of fixed assets of approximately \$65,000 and \$338,000 in 2005 and 2004, respectively, primarily related to the sale of laboratory and computer equipment, which were no longer used in operations as a result of restructuring.

For the year ended December 31, 2005, we recorded income from the sale of intellectual property of \$2,500,000, due to the sale of intellectual property related to the genomic sequence of an undisclosed pathogen to Wyeth. We also recorded a gain on the disposition of marketable securities of approximately \$2,162,000 in exchange for our ownership of common stock of Agencourt Bioscience Corporation, which was recently acquired by Beckman Coulter in a cash transaction.

For the year ended December 31, 2005, we recorded other income of approximately \$43,000, primarily due to miscellaneous license fees related to genomic-based software sold in previous periods.

## **Discontinued Operations**

For the years ended December 31, 2005 and 2004, we recorded income from discontinued operations of approximately \$35,000 and \$208,000, respectively for royalty payments from Agencourt who purchased our genomics services business in March 2003.

## **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 total 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.

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### **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 \$3,381,000 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 32% to \$29,557,000 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 five-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 and an increase of \$3,738,000 in stock based compensation 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. 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 \$4,696,000 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 deformylase 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 and marketing expenses significantly increased to \$34,826,000 in 2004 from \$0 in 2003. This increase was due to the commercial launch of FACTIVE in 2004, which included building a sales and marketing force to promote the sale of FACTIVE tablets. Selling and marketing expenses are expected to increase as we continue to expand our commercialization efforts related to FACTIVE to support a national sales campaign.

General and administrative expenses increased significantly to \$12,981,000 in 2004 from \$6,832,000 in 2003 primarily due to an increase in general and administrative payroll and related costs of approximately \$4,606,000, an increase of approximately \$744,000 in other general and administrative expenses due to the launch of FACTIVE in September 2004 and an increase of \$799,000 in stock based compensation 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 \$4,681,000, for the impairment of the Beaver Street, Waltham, Massachusetts 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.

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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 \$991,000 in 2003. In 2004, interest expense primarily consisted 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 Sanofi Pasteur for the transfer to Sanofi Pasteur 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 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.

### **Liquidity and Capital Resources**

Our primary sources of cash have been from the issuance of debt and equity securities, product discovery alliances, the sale of FACTIVE tablets and co-promotion revenues based on the sale of TESTIM.

As of December 31, 2005, we had total cash, cash equivalents and short-term marketable securities of approximately \$80,044,000, which includes approximately \$11,730,000 in restricted cash. We may need to raise additional capital in the future to fund our operations. In order to facilitate the raising of additional funds, we have filed a shelf-registration statement with the SEC that allows us to sell up to \$100 million of common stock. We believe that, under our current rate of investment in development and commercialization programs, our existing capital resources are adequate to support operations through the end of 2006. There is no assurance, however, that changes in our plans or events affecting our operations will not result in accelerated or unexpected expenditures.



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We have experienced a significant increase in hiring costs in an effort to build an effective sales and marketing organization to commercialize FACTIVE tablets and co-promote TESTIM, expand the medical/development organization to support additional FACTIVE development and commercialization, support the development of Ramoplanin and to build the infrastructure necessary to support these expansions. We expect expenses in the sales and marketing areas to remain at the same level as we continue to promote the sale of TESTIM and commercialize FACTIVE.

*Cash Flows*

Our operating activities used cash of approximately \$96,980,000, \$70,589,000 and \$16,202,000 in 2005, 2004 and 2003, respectively. Cash used in our operating activities for 2005 was primarily a result of our loss from continuing operations of approximately \$88,628,000, adjusted for the gains of approximately \$2,227,000 on the sales of investment and fixed assets, an increase in inventories of approximately \$7,129,000 due to increased demand of FACTIVE tablets, and an increase in accounts receivable of approximately \$1,983,000, as well as decreases in accounts payable of approximately \$2,633,000, accrued expenses and other liabilities of approximately \$4,678,000, clinical trial expense accrual of approximately \$941,000, deferred revenue of approximately \$1,302,000 related to our initial stocking incentive program, accrued facilities impairment charge of approximately \$2,947,000 related to our west coast facility and accrued restructuring charge of approximately \$1,143,000 related to our previous facility in Waltham, Massachusetts. These uses of cash were partially offset by decreases in prepaid expenses and other current assets of approximately \$5,350,000 and \$1,247,000 in interest receivable and an increase in accrued other long-term liabilities of approximately \$993,000 as well as non-cash depreciation and amortization expenses of approximately \$7,974,000 including amortization of intangible assets, stock based compensation, non-cash interest expense and provision for excess and obsolete inventories of approximately \$1,067,000. Cash used in our operating activities for 2004 was due primarily to our loss from continuing operations of approximately \$93,479,000, an increase in inventories of approximately \$6,959,000 to support the launch of FACTIVE, and other increases in an interest receivable, accounts receivable, prepaid expenses and other current assets as well as decreases in accrued facility impairment charge, and clinical trial expense accrual. These uses of cash were partially offset by increases in accounts payable, accrued expenses and other liabilities, deferred revenue, accrued restructuring charge, 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 loss from continuing operations and decreases in accounts payable, clinical trial expense accrual and deferred revenue; 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.

Our investing activities provided cash of approximately \$96,823,000 in 2005, used cash of approximately \$120,236,000 in 2004, and provided cash of approximately \$25,302,000 in 2003. Cash provided by our investing activities in 2005 were primarily related to proceeds from maturities of marketable securities of approximately \$94,694,000, proceeds related to the disposition of Agencourt stock upon its acquisition by Beckman Coulter of approximately \$2,387,000, a decrease of restricted cash of approximately \$5,246,000 related to the payment of convertible note interest, a decrease in other assets of approximately \$471,000, proceeds from sales of fixed assets of approximately \$359,000 and proceeds from notes receivable of approximately \$440,000. Cash provided from investing activities was partially offset by the issuance of notes receivable of approximately \$2,740,000 related to a deposit required in order to lease vehicles for the sales representatives, purchases of marketable securities of approximately \$2,706,000 and purchases of property and equipment of approximately \$1,328,000. 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 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 \$901,000. Cash provided by our investing activities in 2003 was primarily due to proceeds from maturities of

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marketable securities and proceeds from sale of property and equipment. These sources of cash were partially offset by purchases of marketable securities, purchases of property and equipment as well as increases in other assets. Additionally, in 2003 the Company issued a bridge loan of approximately \$6,238,000 to Genesoft in connection with the merger of the two companies in February 2004.

Capital expenditures totaled approximately \$1,328,000 and \$1,532,000 in 2005 and 2004, respectively 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. Capital expenditures in 2003 were approximately \$121,000 primarily consisting of purchases of computer-related equipment.

Our financing activities provided cash of approximately \$997,000 in 2005, primarily due to proceeds from exercise of stock options of approximately \$871,000 and proceeds from the issuance of shares under the employee stock purchase plan of approximately \$417,000, offset by payments of long-term obligations of approximately \$291,000. 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 with 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 approximately \$12,650,000, proceeds from issuance of stock under employee purchase plan and from exercise of stock options 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.

At December 31, 2005, we had net operating loss carryforwards of approximately \$377,305,000 and \$278,981,000 available to reduce federal and state taxable income respectively, if any. In addition, we also had tax research credit carryforwards of approximately \$20,045,000 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.

*Our Outstanding Debt Obligations and Equity Financings*

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 termination of trading of our common stock or a change of control transaction in which substantially all of our common stock is exchanged for consideration other than common stock that is listed on a U.S. national securities exchange or market (such as NASDAQ), holders of these 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 change of control transaction in which all of the consideration paid for our common stock consists of cash, we may have an obligation to pay an additional make-whole premium to the note holders based on a formula set forth in the indenture.

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 which were recorded in investing activities as cash

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flows related to acquisition. 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 of 4,813,547 shares of our common stock representing the payment of accrued interest and related amounts on certain outstanding notes previously issued to such holder by Genesoft.

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 received of approximately \$81 million, net of issuance costs.

**Contractual Obligations**

Our major outstanding contractual obligations relate to our convertible promissory notes, our facility leases and our promotional expense obligations related to our co-promotion agreement with Auxilium Pharmaceuticals. 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):

	2006	2007	2008	2009	2010	Thereafter	Total
Operating leases	\$ 5,780	\$ 5,098	\$ 5,424	\$ 5,613	\$ 5,799	\$ 2,030	\$ 29,744
Sublease contracted income	(3,901)	(1,135)					(5,036)
Current sublease forecasts (a)			(1,685)	(1,732)	(1,778)	(297)	(5,492)
	1,879	3,963	3,739	3,881	4,021	1,733	19,216
Convertible promissory notes, including interest (b,c)	5,346	5,346	5,346	33,904	5,346	158,096	213,384
Co-Promotion Agreement (d)	6,400	2,100					8,500
<b>Total forecasted contractual obligations</b>	<b>\$ 13,625</b>	<b>\$ 11,409</b>	<b>\$ 9,085</b>	<b>\$ 37,785</b>	<b>\$ 9,367</b>	<b>\$ 159,829</b>	<b>\$ 241,100</b>

(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 our 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 or February 6, 2009. 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 approximately \$28.6 million at maturity date includes approximately \$6.2 million of accrued interest payable.

(c) In the quarter ended June 26, 2004, the Company issued \$152,750,000 in principal amount of its 3.5% senior convertible promissory notes due in April 2011. These notes are convertible into the Company's common stock at the option of the holders at a conversion price of \$6.64 per share. We may not redeem the notes at its 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 termination of trading of our common stock or a change of control transaction in which substantially all of our common stock is exchanged for consideration other than common stock that is listed on a U.S. national securities exchange or market (such as NASDAQ), holders of these 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 change of control transaction in which all of the consideration paid for our common stock consists of cash, we may have an obligation to pay an additional make-whole premium to the note holders based on a formula set forth in the indenture. In

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connection with the issuance, we recorded deferred financing costs of \$5,708,000 which is being amortized to interest expense on a straight-line basis over the period the notes are outstanding. A portion of the net proceeds from the offering was used to purchase U.S. government securities as pledged collateral to secure the first six scheduled interest payments on the notes, which are classified as restricted cash on the December 31, 2005 and December 31, 2004 consolidated balance sheets. As part of the issuance, we filed a shelf registration statement relating to the resale of the notes and the common stock issuable upon conversion.

- (d) On April 11, 2005, we entered into a co-promotion agreement with Auxilium Pharmaceuticals, Inc. under which we and Auxilium will co-promote in the U.S. Auxilium's product, TESTIM gel, a topical 1% testosterone gel indicated for the treatment of male hypogonadism. We are obligated to share equally with Auxilium all TESTIM promotional expenses directed at the U.S. primary care physician market audience. Our share of these expenses is expected to be approximately \$6,500,000 in 2006 and approximately \$2,167,000 in the first half of 2007. The agreement provides for two extension terms at our option (provided that we meet certain performance targets), which if exercised, will result in similar contractual obligations for the next four years through April 2011.

**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. Our investment policy limits the amount of our credit exposure to any one issue, issuer, and type of instrument. Due to the nature of our investments and the investment policies and procedures, we have determined that the risks associated with the interest rate fluctuations related to these financial instruments are not material to our business.

As of December 31, 2005 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 \$22,310,000 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 our 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.

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### **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.

### **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, 2005 in connection with the preparation of this annual report. They concluded that the disclosure 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 as of December 31, 2005 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, 2005.

Our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2005 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, 2005, 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, 2005, 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, 2005, 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, 2005 and 2004, 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, 2005 of Oscient Pharmaceuticals Corporation and our report dated March 3, 2006 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts

March 3, 2006

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**Item 9B. OTHER INFORMATION**

Luke Evin informed the Company on March 10, 2006 that he will not stand for re-election to the Board of Directors at our Annual Meeting of Shareholders to be held on June 6, 2006.

David Singer informed the Company on March 6, 2006 that he will not stand for re-election to the Board of Directors at our Annual Meeting of Shareholders to be held on June 6, 2006.

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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 our proxy statement for the Annual Meeting of Shareholders to be held on June 6, 2006.

**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 2006 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 2006 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 2006 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 our code of ethics and conduct which is available free of charge on our website ([www.oscient.com](http://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](mailto: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 our 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.

**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 2006 Annual Meeting of Stockholders. Such information is incorporated herein by reference.



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**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 2006 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 2006 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 2006 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

**Table of Contents****PART IV****Item 15. Exhibits and Financial Statement Schedules**

(a) FINANCIAL STATEMENTS See Index to Consolidated Financial Statements appearing on page F-1.

(3) List of Exhibits

<b>Exhibit No.</b>	<b>Description</b>
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)
3.12	Amendment dated April 13, 2004 to Restated Articles of Organization(43)
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)
4.7	Indenture dated as of May 10, 2004(44)
4.8	Pledge Agreement dated as of May 10, 2004(44)
4.9	Registration Rights Agreement dated May 10, 2004(44)
4.10	Indenture dated as of May 10, 2004(44)
4.11	Pledge Agreement dated as of May 10, 2004(44)
4.12	Registration Rights Agreement Dated May 10, 2004(44)
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)



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<b>Exhibit No.</b>	<b>Description</b>
10.3	Amendment dated November 4, 1986 to the Genome Therapeutics Corp. (f/k/a Collaborative Research) Incentive Savings Plan dated March 1, 1985(6)
10.4	1991 Stock Option Plan and Form of Stock Option Certificate(10)
10.5	Lease dated November 17, 1992 relating to certain property in Waltham, Massachusetts(11)
10.6	Lease dated June 3, 1993 relating to certain property in Waltham, Massachusetts(11)
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	Lease amendment dated November 15, 1996 to certain property in Waltham, MA(16)
10.10	1997 Directors' Deferred Stock Plan(19)
10.11	1997 Stock Option Plan(19)
10.12	Registration Rights Agreement between the Company and bioMerieux Alliance as dated September 30, 1999(23)
10.13	2001 Incentive Plan(24)
10.14	Stock Option Agreements with Steven M. Rauscher(24)
10.15	Employment Letter with Steven M. Rauscher(26)
10.16	Purchase Agreement dated March 5, 2002 among Smithfield Fiduciary LLC, The Tail Wind Fund, Ltd. and the Company(27)
10.17	Registration Rights Agreement dated March 5, 2002 among Smithfield Fiduciary LLC, The Tail Wind Fund, Ltd. and the Company(27)
10.18	License and Supply Agreement between the Company and Biosearch Italia, S.P.A., dated October 8, 2001(29)*
10.19	Stock Purchase Agreement between the Company and Amgen Inc., dated December 20, 2002(30)*
10.20	Letter Agreement between the Company and Biosearch Italia, S.P.A., dated October 22, 2002 (30)*
10.21	Employment Letter with Stephen Cohen(31)
10.22	Form of Subscription Agreement for Private Placement(34)
10.23	Registration Rights Agreement for Private Placement(34)
10.24	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)
10.25	Registration Rights Agreement dated as of November 17, 2003, by and between Genome Therapeutics Corp. and certain creditors of GeneSoft Pharmaceuticals, Inc.(37)
10.26	Amendment to Employment Agreement dated as February 5, 2004 between Genome Therapeutics Corp. and Steven M. Rauscher(38)
10.27	Amendment to Employment Agreement dated February 5, 2004 between Genome Therapeutics Corp. and Stephen Cohen(38)
10.28	Employment letter with Gary Patou, M.D. dated January 11, 2004(38)

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<b>Exhibit No.</b>	<b>Description</b>
10.29	License and Option Agreement dated October 22, 2002 between Genesoft Pharmaceuticals, Inc. and LG Life Sciences, Ltd.(39)*
10.30	Amendment No. 1 to License and Option Agreement dated November 21, 2002 by and between Genesoft Pharmaceuticals, Inc. and LG Life Sciences, Ltd.(38)
10.31	Amendment to No. 2 to License and Option Agreement dated December 6, 2002 by and between Genesoft Pharmaceuticals, Inc. and LG Life Sciences, Ltd.(39)*
10.32	Amendment No. 3 to License and Option Agreement dated October 16, 2003 by and between Genesoft Pharmaceuticals, Inc. and LG Life Sciences, Ltd.(39)*
10.33	Genome Therapeutics Corp. Employee Stock Purchase Plan as amended through April 13, 2004(42)
10.34	Genome Therapeutics Corp. 2001 Incentive Plan as amended through April 13, 2004(42)
10.35	Employment Letter with Dominick Colangelo(40)
10.36	Employment Letter with Antonius Bunt(40)
10.37	Co-Promotion Agreement dated April 11, 2005 between Auxilium Pharmaceuticals, Inc. and Oscient Pharmaceuticals Corp.(41)*
10.38	Amendment No. 4 to License and Option Agreement dated March 31, 2005 by and between Genesoft Pharmaceuticals, Inc. and LG Life Sciences, Ltd.(41)*
10.39	Form of Incentive Stock Option(45)
10.40	Form of Nonstatutory Stock Option(45)
10.41	Form of Restricted Stock Award(45)
12.1	Statement re: Computation of Ratios(46)
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm(46)
31.1	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act(46)
31.2	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act(46)
32.1	Certification of the Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act(46)
32.2	Certification of the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act(46)

\* 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's 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.

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- (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 as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ended March 27, 2004.
- (39) Filed as an exhibit to the Company s Quarterly Report on Form 10-Q/A for the quarter ended March 27, 2004.
- (40) Filed as an exhibit to the Company s 10-K for the year-ended December 31, 2004 and incorporated herein by reference.
- (41) Filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ended March 31, 2005.
- (42) Filed as an exhibit to the Company s Registration Statement on Form S-8 (333- 116707) and incorporated herein by reference.
- (43) Filed as an exhibit to the Company s Registration Statement on Form S-3 (333-1 28735) and incorporated herein by reference.
- (44) Filed as an exhibit to the Company s Registration Statement on Form S-3 (333-118026) and incorporated herein by reference.
- (45) Filed as an exhibit to the Company s 8-K filed on December 27, 2005 and incorporated herein by reference.
- (46) 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 10, 2006

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 dates indicated.

/s/ STEVEN M. RAUSCHER	Director, President and Chief Executive Officer	March 10, 2006
<b>Steven Rauscher</b>		
/s/ STEPHEN COHEN	Senior Vice President and Chief Financial Officer (Chief Financial and Accounting Officer)	March 10, 2006
<b>Stephen Cohen</b>		
/s/ DAVID K. STONE	Chairman of the Board and Director	March 10, 2006
<b>David K. Stone</b>		
/s/ LUKE EVNIN	Director	March 10, 2006
<b>Luke Evnin</b>		
/s/ ROBERT J. HENNESSEY	Director	March 10, 2006
<b>Robert J. Hennessey</b>		
/s/ PAMELA J. KIRBY	Director	March 10, 2006
<b>Pamela Kirby</b>		
/s/ WILLIAM S. REARDON	Director	March 10, 2006
<b>William S. Reardon</b>		
/s/ NORBERT G. RIEDEL	Director	March 10, 2006
<b>Norbert G. Riedel</b>		
/s/ GARY PATOU	Director	March 10, 2006
<b>Gary Patou, M.D.</b>		
/s/ DAVID SINGER	Director	March 10, 2006
<b>David Singer</b>		



/s/ JOHN E. VORIS