

OSCIENT PHARMACEUTICALS CORP

Form 10-K

February 06, 2008

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

**FORM 10-K**

(Mark one)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended: December 31, 2007

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934  
Commission file number: 0-10824

**OSCIENT PHARMACEUTICALS CORPORATION**

(Exact name of registrant as specified in its charter)

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**Massachusetts**  
(State or other jurisdiction)

**04-2297484**  
(IRS employer

of incorporation or organization)  
**1000 Winter Street, Suite 2200**

identification number)

**Waltham, Massachusetts**  
(Address of principal executive offices)

**02451**  
(Zip Code)

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

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

<b>Title of Each Class</b>	<b>Name of Each Exchange on Which Registered</b>
<b>Common Stock, \$.10 Par Value</b>	<b>NASDAQ Global Market</b>

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

**None.**

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, 2007, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was \$56,587,564 as reported on the NASDAQ Global Market. The number of shares outstanding of the registrant's common stock as of February 1, 2008 was 13,764,113.

**DOCUMENTS INCORPORATED BY REFERENCE**

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Portions of the registrant's proxy statement for use at its 2008 Annual Meeting of Shareholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

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**Oscient Pharmaceuticals Corporation**

**ANNUAL REPORT**

**ON FORM 10-K**

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### PART I

#### 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 ANTARA and FACTIVE, our discount and rebate programs for ANTARA and FACTIVE, possible partnering or other strategic opportunities for the continued development of Ramoplanin, potential marketing approval of FACTIVE in the European Union, 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, project, and expect and similar expressions are intended to identify forward-looking statements. 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 forward-looking statements.

#### Item 1. Business

##### OVERVIEW

Oscient Pharmaceuticals Corporation ( we , us , or the Company ) is a commercial-stage pharmaceutical company marketing Food and Drug Administration (FDA)-approved products in the United States. Our strategy is to grow the sales of our existing products and to gain access to new products via transactions, including acquisition, in-licensing and co-promotion. We have developed a commercial infrastructure, including a national sales force calling on targeted primary care physicians, cardiologists, endocrinologists and pulmonologists in the United States.

We currently market two products: ANTARA<sup>®</sup> (fenofibrate) capsules, a cardiovascular product, and FACTIVE<sup>®</sup> (gemifloxacin mesylate) tablets, a fluoroquinolone antibiotic. ANTARA is approved by the FDA to treat hypercholesterolemia (high blood cholesterol) and hypertriglyceridemia (high triglycerides) in combination with a healthy diet. We license the rights to ANTARA from Ethypharm S.A. of France (Ethypharm) and began promoting ANTARA in late August 2006. In 2007, ANTARA generated approximately \$59 million in net revenues. FACTIVE is indicated for the treatment of community-acquired pneumonia of mild to moderate severity, or CAP, and acute bacterial exacerbations of chronic bronchitis, or AECB. We license the rights to gemifloxacin, the active ingredient in FACTIVE tablets, from LG Life Sciences of the Republic of Korea (LG Life Sciences) and launched FACTIVE in the U.S. market in September 2004. In 2007, FACTIVE generated approximately \$20 million in net revenues.

Additionally, we have a novel, late-stage antibiotic candidate, Ramoplanin for the treatment of *Clostridium difficile*-associated disease, or CDAD. We have made the strategic decision to concentrate our financial resources on building our revenues for products promoted to community-based physicians in the United States and are currently seeking to out-license, co-develop or sell the rights to Ramoplanin to a partner.

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### **ANTARA**

#### **The Fenofibrate and Cholesterol-Treatment Markets**

Nearly 37 million Americans have total cholesterol values above recommended levels and heart disease remains the number one cause of death in the U.S. Abnormal cholesterol and lipid levels, known as dyslipidemia, can lead to the development of atherosclerosis, a dangerous hardening of blood vessels and a primary cause of coronary heart disease. Managing cholesterol levels is a complex undertaking and several therapeutic options are available to treat different types of abnormalities. Statins are the standard of care for lowering high levels of LDL-C (low density lipoprotein cholesterol). Fenofibrate products have demonstrated their utility in managing atherogenic dyslipidemia or mixed dyslipidemia (also known as lipid abnormalities) which are characterized by high triglycerides, low HDL-C (high density lipoprotein cholesterol), high levels of remnant-like particle cholesterol and a high proportion of cholesterol carried by small, dense LDL particles. Other drugs commonly used to treat lipid abnormalities include niacin and omega-3 fatty acids.

In 2007, total U.S. sales of fenofibrate products were approximately \$1.7 billion, a 12% increase over 2006 sales. The fenofibrate market has experienced a 25% average annual growth in sales since 2003.

#### **Indications and Efficacy**

ANTARA is a once-daily formulation of fenofibrate approved for use in combination with a diet restricted in saturated fat and cholesterol to reduce elevated LDL-C ( bad cholesterol), triglyceride and apolipoprotein B (free floating fats in the blood) levels and to increase HDL-C ( good cholesterol) in adult patients with high cholesterol or an abnormal concentration of lipids in the blood. Fenofibrate products work primarily to lower triglycerides and increase HDL-C. ANTARA received FDA approval in November 2004 and is approved and marketed in 43 mg and 130 mg doses. The predominantly prescribed dose is 130 mg while the 43 mg dose is generally used for titration and in patients with impaired renal function. ANTARA was approved based in part on demonstrating its bioequivalence to Abbott Laboratories fenofibrate product Tricor<sup>®</sup>, meaning that, under FDA guidelines, the bioequivalence of the two products does not differ significantly when the two products are given under similar conditions. ANTARA was also studied in the Triglyceride Reduction in Metabolic Syndrome study, known as TRIMS, to measure the impact of ANTARA on cholesterol levels in patients with multiple cardiovascular risk factors and to assess the use of ANTARA without regard to meals.

In the treatment of hypercholesterolemia, ANTARA is approved as adjunctive therapy to diet to reduce elevated LDL-C, total cholesterol (total-C), triglycerides and apolipoprotein B (apo B) and to increase HDL-C in adult patients with primary hypercholesterolemia or mixed dyslipidemia. The effects of fenofibrate at a dose equivalent to 130 mg ANTARA per day were assessed in four randomized, placebo-controlled, double-blind, parallel-group studies. Fenofibrate therapy lowered LDL-C, total-C, and the LDL-C/HDL-C ratio. In these studies, fenofibrate therapy also lowered triglycerides, raised HDL-C and significantly reduced apo B as compared with placebo.

ANTARA is also indicated as an adjunctive therapy to diet for the treatment of hypertriglyceridemia, which affects an estimated 10% of American men over the age of 30 and 10% of American women over the age of 55. In clinical studies, the effects of fenofibrate on serum triglycerides were studied in two randomized, double-blind, placebo-controlled clinical trials of 147 hypertriglyceridemic patients for eight weeks. In patients with hypertriglyceridemia, treatment with fenofibrate at dosages equivalent to 130 mg ANTARA per day effectively decreased very low density lipoprotein (VLDL) triglycerides and VLDL cholesterol.

*Mechanism of Action:* ANTARA increases lipolysis and elimination of triglyceride-rich particles from plasma by activating lipoprotein lipase and reducing production of apoprotein C-III (an inhibitor of lipoprotein lipase activity). The resulting decrease in triglycerides produces an alteration in the size and composition of LDL from small, dense particles (which are thought to be atherogenic due to their susceptibility to oxidation), to large

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buoyant particles. These larger particles have a greater affinity for cholesterol receptors and are catabolized rapidly. ANTARA also activates PPAR-alpha, which induces an increase in the synthesis of apoproteins A-I, A-II and HDL-cholesterol.

*Competitive Advantages:* The TRIMS study produced exclusive clinical data for ANTARA. In the study, ANTARA was evaluated in patients with elevated triglyceride levels and multiple cardiovascular risk factors. Of the 146 patients studied, 70% had hypertension and 32% had diabetes. The double-blind, placebo-controlled trial measured levels of total cholesterol, triglycerides, HDLs and LDLs, as well as other types of cholesterol, during eight weeks of therapy. In the study, ANTARA demonstrated the ability to reduce triglyceride and increase HDL-C levels after two weeks of therapy. At the end of therapy, patients treated with ANTARA had a statistically significant 37% reduction in their triglyceride levels and a statistically significant 14% increase in their HDL levels. ANTARA is distributed in 130 mg and 43 mg formulations, as compared to the 145 mg and 48 mg formulations of Tricor, which is marketed by Abbott Laboratories.

## **License Agreement**

On August 18, 2006, we acquired the rights to ANTARA in the United States from Reliant Pharmaceuticals Inc. (Reliant) for \$78.0 million plus approximately \$4.3 million for ANTARA inventory, excluding estimated transaction costs. Under the terms of our acquisition of ANTARA, we assumed certain of Reliant's liabilities related to ANTARA, including obligations to make certain royalty and milestone payments on sales of ANTARA, and we were assigned rights to an exclusive license from Ethypharm S.A. (Ethypharm). In order to maintain the exclusivity of our rights, we must achieve minimum annual sales in the United States until February 2012 or alternatively compensate Ethypharm for any shortfall. During the term of the agreement with Ethypharm, we are obligated to pay a royalty on net sales of ANTARA in the U.S., including a royalty on other fenofibrate monotherapy products in formulations and dosage forms that may be substantially similar or identical to ANTARA developed by us. The license term expires in February 2020 and, absent notice of termination by either party, automatically renews for consecutive periods of two (2) years each. Under the terms of the agreement, at our option, Ethypharm is obligated to manufacture and deliver to us finished ANTARA capsules or to deliver bulk product to us for encapsulation and packaging. Ethypharm has a right of first refusal on any divestiture of the ANTARA rights by us. Additional Oscient obligations under the Ethypharm agreement include using commercially reasonable efforts to maintain a sales force of at least 150 representatives through February 2008 and funding a portion of the active pharmaceutical ingredient safety stock that Ethypharm is required to maintain.

Pursuant to the terms of our acquisition of ANTARA from Reliant, we also acquired the New Drug Application, or NDA, and the Investigational New Drug application, or IND, covering the ANTARA products in the United States, clinical data, inventory, the ANTARA® trademark in the United States and certain related contracts and licenses covering intellectual property rights related to the ANTARA products. We also assumed certain of Reliant's liabilities related to the ANTARA products.

We are not required to pay Reliant a royalty on the sale of the ANTARA products; however, we are required to pay a low single-digit royalty to Reliant for a specified time period on net sales of any line extensions and improvements to the ANTARA products which we develop, which include all products containing fenofibrate as their active pharmaceutical ingredient. We do not currently pay royalties to Reliant. We also agreed that we would not, at any time prior to August 2016, develop or sell any product in the United States that is a combination of fenofibrate and an omega-3 compound without the prior written consent of Reliant. On December 19, 2007, Reliant was acquired by GlaxoSmithKline.

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### **FACTIVE**

#### **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 ninth leading cause of death in the U.S. Sales of antibiotics in the U.S. totaled \$14 billion in 2007. Within the antibiotic market, fluoroquinolones, a product class with close to \$3.9 billion in annual sales in the U.S. in 2007, have been gaining market share at the expense of older classes of antibiotics, according to Wolters Kluwer, a leading provider of pharmaceutical market data. This is a trend that is expected to continue as resistance to older antibiotic classes increases.

The principal classes of antibiotics include beta-lactams, fluoroquinolones, macrolides, tetracyclines, aminoglycosides, glycopeptides and trimethoprim combinations. Bacterial resistance to existing antibiotics has increased 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.

*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 approximately 9 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 AECEB, is typically effective in reducing the course of illness for patients. Fluoroquinolones are frequently used to treat AECEB due to their activity versus *Haemophilus influenzae* and *Moraxella catarrhalis*, two of the most common causes of these infections. Newer fluoroquinolones have enhanced activity versus *Streptococcus pneumoniae*, or *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. Of the estimated 4 to 5 million cases per year of CAP, nearly 1 million cases occur in patients over the age of 65. CAP cases result in approximately 10 million physician visits and as many as 1 million hospitalizations 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 on a case by case basis. 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 penicillins and macrolides has increased significantly, and in many cases, fluoroquinolones are now recommended as a first line of therapy due to their efficacy against a wide range of respiratory pathogens, including many antibiotic resistant strains. The most recent treatment guidelines from the Infectious Diseases Society of America and the American Thoracic Society recommend fluoroquinolones as a first-line treatment for certain higher-risk patients with CAP and as therapy for treating patients with pneumonia in geographic regions of the U.S. with high levels of macrolide-resistant *S. pneumoniae*.

#### **Indications and Efficacy**

FACTIVE is a member of the fluoroquinolone class of antibiotics. In April 2003, FACTIVE was approved by the FDA for the five-day treatment of AECEB and seven-day treatment of CAP of mild to moderate severity. In July 2003, FACTIVE was also approved by the FDA to treat CAP caused by multi-drug resistant *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 May 2007, FACTIVE was approved by the FDA for the five-day treatment of CAP.



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FACTIVE has potent *in vitro* activity against a wide range of Gram-positive, Gram-negative and atypical pathogens, including key respiratory pathogens, such as *S. pneumoniae*, *H. influenzae* and *M. catarrhalis*. FACTIVE is bactericidal at clinically achievable concentrations. Gemifloxacin, the active ingredient in FACTIVE, has minimum inhibitory concentrations, or MICs, as low as 0.032 µg/ml for *S. pneumoniae*. In clinical trials, FACTIVE has been 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 300 scientific articles. Among the research published are data from a study involving 438 subjects indicating that a statistically significant higher percentage of patients treated with FACTIVE (71%) remained free of AECB recurrences than those treated with a comparator agent (58.5%) 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 development program for FACTIVE included 19 Phase III trials in respiratory tract infections. FACTIVE was studied for the treatment of acute bacterial exacerbations of chronic bronchitis in three pivotal, non-inferiority, double-blind, randomized, active-controlled clinical trials using 320 mg once daily for five-days. In these principal Phase III AECB studies, FACTIVE given once daily for five-days was at least as effective as the comparators given for seven-days, with clinical response rates in the FACTIVE arms ranging from 85.4% to 93.6%. FACTIVE was also studied for the treatment of CAP in three double-blind, randomized, active-controlled clinical studies, one open, active-controlled study, and two uncontrolled studies. The results of these studies showed that gemifloxacin was effective in the treatment of mild to moderate CAP.

*Safety and Tolerability:* FACTIVE tablets have been studied in approximately 8,000 patients in clinical trials and we estimate that to date, nearly 795,000 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 across all durations of therapy, 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, particularly females. In clinical trials conducted in 3,696 patients treated with five-days of FACTIVE therapy, the rate of rash reported was 1.1% vs. 0.7% for comparator antibiotics. 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.

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

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 FACTIVE has low potential for generating bacterial resistance.

FACTIVE can be dosed once daily, with short courses of therapy (five-days) for both AECB and CAP.

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FACTIVE is effective in the treatment of CAP due to penicillin-resistant *S. pneumoniae* and due to MDRSP. In clinical trials, of 22 patients with MDRSP treated with FACTIVE for seven-days, 19 (87%) achieved both clinical and bacteriological success at follow-up.

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

FACTIVE has composition of matter patent protection which extends into 2018, longer than the composition of matter patent protection for any currently marketed fluoroquinolone or other antibiotic widely used to treat respiratory tract infections.

*Post-Marketing Commitments:* As a post-marketing commitment to the FDA, we completed a Phase IV trial of FACTIVE. This prospective, randomized study examined the activity of FACTIVE tablets (5,000 patients) versus an active comparator (2,500 patients) in treating patients with mild to moderate CAP or AECB. The study included patients of different ethnicities so that safety information in populations not substantially represented in the existing clinical trial program could be collected, specifically as it relates to rash. This Phase IV trial was initiated in the fall of 2004 and was completed in January 2007. 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 describing the number of prescriptions issued, including refills and the diagnoses for which the prescriptions are dispensed. The final report of the utilization study is scheduled for submission in the first half of 2008. In the future, we need only to provide the FDA with annual reports containing safety information.

### **Additional Development of FACTIVE**

*Five-Day Treatment of CAP:* We 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 previously approved seven-day course of treatment. On September 21, 2006, we received an approvable letter from the FDA for the supplemental New Drug Application (sNDA) seeking approval for the five-day treatment of CAP with FACTIVE tablets. In accordance with the letter, we provided clarification and additional interpretation regarding certain data included in the application to assist the FDA in its evaluation. On May 1, 2007, the FDA approved FACTIVE for the five-day treatment of CAP.

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, randomized, 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.

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*Acute Bacterial Sinusitis:* As part of the FACTIVE development program, several studies relating to acute bacterial sinusitis, or ABS, were completed, and, in November 2005, we filed an sNDA for ABS. In September 2006, the FDA's Anti-Infective Drugs Advisory Committee voted not to recommend approval of this sNDA. In November 2006, we voluntarily withdrew our sNDA seeking approval of the ABS indication.

*FACTIVE IV:* An intravenous formulation of gemifloxacin has also been studied. If we elect to further pursue such a formulation, additional formulation development will be necessary before initiating a bioequivalence study.

### **License Agreement with LG Life Sciences**

We license the rights to gemifloxacin, the active ingredient in FACTIVE tablets, from LG Life Sciences. 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, Vatican City, Poland, Czech Republic, Slovakia, Slovenia, Hungary, Estonia, Latvia, Lithuania, Liechtenstein, Malta, Cyprus, Romania, Bulgaria, Croatia, Serbia and Montenegro, Bosnia and Herzegovina, Albania and the Former Yugoslav Republic of Macedonia. 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 patent term could extend further in countries outside of the U.S. 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 active pharmaceutical ingredient, or API. LG Life Sciences currently supplies the FACTIVE API from its manufacturing facility in South Korea.

The agreement with LG Life Sciences also requires that we achieve a minimum gross sales level of \$30 million from our licensed territories over a 12-month period of time starting on the third anniversary from the launch of FACTIVE in the U.S. in 2004 which, if not met, LG Life Sciences could elect to terminate the agreement and have the technology be 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.

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 (i) the expiration of the patents covering FACTIVE in such country or (ii) the expiration of data exclusivity in Mexico, Canada or the European Union respectively, or 2014 in the U.S. We are also obligated to make aggregate milestone payments of up to approximately \$40 million (not including payments to LG Life Sciences previously made pursuant to up-front obligations or achievements of certain milestones) including milestone payments required by the amendments described below upon achievement of additional regulatory approvals and sales thresholds.

### **Collaborations and Partnerships for FACTIVE**

*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 market FACTIVE tablets in Mexico to Pfizer Mexico. In exchange for those rights, Pfizer Mexico has made an up-front payment and has agreed to pay milestone payments upon obtaining certain regulatory approvals and sales goals, as well as

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royalties on future sales. The up-front payment is being recognized as revenue over the term of our continuing obligations under the agreement. 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 API 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 nine months prior written notice. Upon termination, Pfizer Mexico is obligated to assign any and all rights to regulatory approvals in Mexico to us or our designee.

In October 2006, Pfizer Mexico launched its promotion and marketing of FACTIVE-5 in Mexico for the five-day treatment of acute bacterial exacerbations of chronic bronchitis (AECB), acute bacterial sinusitis (ABS) and community-acquired pneumonia (CAP).

*Abbott Laboratories Ltd.* On August 9, 2006, we granted the commercialization rights to FACTIVE tablets in Canada to Abbott Laboratories, Ltd. (Abbott Canada), the Canadian affiliate of Abbott. In exchange for those rights, Abbott Canada agreed to a transfer price on product purchases and to make certain payments to us upon achievement of certain regulatory and sales milestones. FACTIVE tablets are currently approved in Canada for the five-day treatment of AECB. We subsequently amended the agreement on January 31, 2008 whereby Abbott Canada's development and commercialization obligations were substantially reduced. In accordance with the terms of the amendment, Abbott Canada will continue to maintain FACTIVE tablets in its current product price list and it will continue to pay us a transfer price on FACTIVE tablets purchases. Abbott Canada is not required to pursue the CAP and ABS indications. Additionally, the amendment provides that we can terminate the agreement at any time with prior notice to Abbott Canada and Abbott Canada can terminate with prior notice to us after November 30, 2008.

*Menarini International Operation Luxembourg SA.* We entered into a License, Supply and Marketing Agreement with Menarini International Operation Luxembourg SA (Menarini), a wholly-owned subsidiary of Menarini Industrie Farmaceutiche Riunite S.r.l. dated December 28, 2006, whereby we sublicensed our rights to sell FACTIVE tablets in the European Union to Menarini. Under the terms of our agreement, Menarini is responsible for obtaining regulatory approval for FACTIVE in the European Union, and Oscient has agreed to reimburse Menarini for expenses associated with such regulatory development up to an agreed limit. Menarini has also paid us an up-front payment which is being recognized over the term of our continuing obligations under the agreement of approximately thirty-three months. Menarini has also agreed to pay us milestone payments upon obtaining certain regulatory and reimbursement approvals and upon achieving certain annual net sales goals, which could total up to \$23.0 million, if all the milestones are achieved. Menarini will pay us a transfer price on purchases of the active pharmaceutical ingredient, or API, for FACTIVE, which is determined based on a percentage of quarterly sales of FACTIVE by Menarini in Europe. Menarini is also obligated to exclusively purchase from us, and we must exclusively supply, all API for FACTIVE to be sold in Europe for the earlier of (i) the expiration of the life of certain patents covering the product or (ii) expiration of data exclusivity. Our agreement with Menarini may be terminated by either party upon the occurrence of certain termination events, including Menarini's right to terminate if the European regulatory authorities do not recommend approval of FACTIVE at various stages of the approval process with a package insert, or label, that meets certain requirements as to the safety, dosing and indications for which FACTIVE may be prescribed. Menarini may also terminate the agreement if it does not receive approval for reimbursement from European member countries that is above a certain minimum price per tablet. Upon termination, Menarini is obligated to assign any and all rights to regulatory approvals in the European Union to Oscient or its designee.

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### **RAMOPLANIN**

#### ***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 to 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.

Over 400,000 patients are treated in U.S. hospitals each year for CDAD. CDAD is associated with an average increased hospital stay 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 in the U.S.

Two studies published in *The New England Journal of Medicine* in December 2005 describe a new strain of *C. difficile*, one that produces 16 to 23 times more toxins *in vitro* than do other strains, thus potentially contributing to its virulence. The very high incidence and mortality rates are of particular concern with this new strain. 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. However, recent relapse rates have increased to 28%. The use of oral vancomycin has been associated with the emergence of vancomycin-resistant organisms, including vancomycin-resistant enterococci, or VRE. Resistance has also been reported for metronidazole.

#### **Ramoplanin Overview**

In October 2001, we in-licensed U.S. and Canadian rights to Ramoplanin from Vicuron Pharmaceuticals Inc., or 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.

In 2004, we completed a 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 to 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.

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We agreed with the FDA to a Special Protocol Assessment regarding the specific components of a Phase III program that, if completed successfully, would support regulatory approval for the indication. On January 8, 2008, the United States Patent and Trademark Office (USPTO) issued us a patent relating to methods of use of Ramoplanin for the treatment of CDAD.

*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:* In exchange for the assignment of the rights for Ramoplanin under the acquisition agreement with Pfizer, we made a one-time, up-front payment to Pfizer and agreed to 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.

With the acquisition of ANTARA, we have made the strategic decision to concentrate our financial resources on building our revenues for products promoted to community-based physicians in the United States and are currently seeking to out-license, co-develop or sell our rights to Ramoplanin to a partner. There can be no assurance that we will be able to license or divest Ramoplanin to a partner on acceptable terms, or at all.

## **SALES AND MARKETING**

We market ANTARA and FACTIVE through our sales and marketing organization in the U.S, which is currently comprised of approximately 270 field sales personnel, including sales representatives, district managers and regional sales directors. Sales and marketing functions are located at our New Jersey office. Our sales representatives focus on community-based physicians and opinion leaders who are potential high prescribers of fluoroquinolones and/or fenofibrate products. We have also built a team of professionals with experience in insurance and government reimbursement, medical affairs and marketing. Our strategy is to continue to leverage our existing commercial infrastructure through the acquisition, in-license or co-promotion of additional marketed products to market to community-based physicians in the United States. Longer term, we anticipate expanding our commercial infrastructure to reach additional physicians.

Our strategy includes granting commercialization rights to FACTIVE tablets in territories outside of the U.S. to third parties to leverage the additional resources that a pharmaceutical marketing partner with expertise in such countries can provide. Thus, we have partnered with following entities:

On February 6, 2006, we sublicensed our rights to sell FACTIVE tablets in Mexico to Pfizer, S.A. de C.V. (Pfizer Mexico), the largest pharmaceutical company in Mexico. Pfizer Mexico is commercializing FACTIVE for community-acquired pneumonia, acute bacterial exacerbations of chronic bronchitis and acute bacterial sinusitis with three national field sales forces and one specialty field sales

force.

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On August 9, 2006, we granted the commercialization rights to FACTIVE tablets in Canada to Abbott Laboratories, Ltd. (Abbott Canada), the Canadian affiliate of Abbott; however, on January 31, 2008, we amended the agreement whereby Abbott Canada's obligations to commercialize FACTIVE tablets were substantially reduced.

On December 27, 2006, we sublicensed our rights to sell FACTIVE tablets in Europe to Menarini International Operation Luxembourg SA (Menarini), the second largest primary care pharmaceutical company in Europe. Menarini is responsible for obtaining regulatory approval for FACTIVE in Europe and will leverage its regulatory and marketing experience to pursue approval and launch of FACTIVE in Europe.

## **COMPETITION**

The pharmaceutical industry generally is 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 products 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 appropriate regulatory approvals for our product candidates in a cost-efficient and timely manner and subsequently remain in regulatory compliance,

our ability to secure adequate reimbursement for our products from public and private healthcare payors,

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 or in-license agreements or product acquisitions,

our ability to secure sufficient capital resources to fund our clinical development and sales and marketing operations, and

our ability to secure sufficient capital resources to execute transactions to gain access to new products.

Because we rely primarily on in-licensing, co-promotion 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, co-promotion 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.



**ANTARA**

ANTARA is a fenofibrate product approved by the FDA to treat hypercholesterolemia and hypertriglyceridemia in combination with a healthy diet. The marketing of branded versions of fenofibrate could reduce our net sales of ANTARA and adversely impact our revenues. The primary competition for ANTARA in the fenofibrate market is Tricor, a product manufactured by Abbott Laboratories, which accounted for approximately 92% of U.S. fenofibrate sales for the twelve month period ended December 31, 2007. ANTARA also competes with Triglide®, a fenofibrate marketed by Sciele Pharma, Inc., which accounted for approximately 2% of U.S. fenofibrate sales for the twelve month period ended December 31, 2007.

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Additionally, ANTARA competes with Lipofen, a 150 mg fenofibrate product, which was recently launched and is currently being marketed by ProEthic Pharmaceuticals, Inc. LifeCycle Pharma A/S recently announced the FDA approval of their 120 mg branded fenofibrate product, which had been filed with the FDA in late 2006 referencing ANTARA in accordance with the provisions of section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act. LifeCycle Pharma granted Sciele Pharmaceuticals rights to market its fenofibrate product in North America, which when launched can also be expected to compete with ANTARA.

Several generic versions of fenofibrate in varying doses are also available for the treatment of dyslipidemias. Revenues from these products accounted for approximately 2% of total U.S. sales of fenofibrate products in 2007. In May 2005, Teva Pharmaceutical Industries, Ltd. (Teva) obtained FDA approval to market a generic version of Abbott Laboratories' 160 mg Tricor tablet (which is no longer marketed or sold). In addition, Solvay S.A., Abbott Laboratories' partner announced on January 23, 2008, that Teva had filed an Abbreviated New Drug Application (ANDA) with a Paragraph IV certification seeking the approval of a generic version of Tricor 145 mg. If a generic version of Abbott Laboratories' Tricor 145 mg product is approved by the FDA, the percentage of total revenues attributable to generic fenofibrate products would likely increase. There are also several other FDA-approved products and products in development for similar indications as ANTARA which could compete with ANTARA, including statins, omega-3 fatty acids, niacin, ezetimibe and fixed-dose, combination products.

The growth of any of these branded products or the marketing of generic fenofibrate products could result in a decrease in ANTARA sales, create pressure on the price at which we are able to sell ANTARA, reduce our profit margins, reduce our net sales of ANTARA and adversely impact our revenues.

## **FACTIVE**

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 (levofloxacin, ciprofloxacin and moxifloxacin), macrolides (clarithromycin and azithromycin) and penicillins (amoxicillin/clavulanate potassium).

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 composition of matter patents which have gone or will be going off patent at dates ranging from 2003 to 2016. 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.

## **Ramoplanin**

Ramoplanin is in clinical development for the treatment of CDAD. We are aware of two products currently utilized in the marketplace: Vancocin® pulvules (vancomycin), a product marketed by ViroPharma Inc., and metronidazole, a generic product, for treatment of this indication. We are also aware of several other companies with products in development for the treatment of CDAD.

## **Legacy Assets**

Our alliance-related product development programs are 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.

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### **GOVERNMENT REGULATION**

Regulation by governmental entities in the United States and other countries will be a significant factor in the development, manufacturing, distribution 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 require review and approval of extensive data in order to permit commercial marketing.

Virtually all aspects of our activities are regulated by federal and state statutes and regulations, and government agencies. The research, development, manufacturing, processing, packaging, labeling, distribution, sale, advertising, promotion, import and export of our products, and disposal of waste products arising from these activities, are subject to regulation by one or more federal agencies and their state equivalents, including the FDA, the Consumer Product Safety Commission, the Occupational Safety and Health Administration and the Environmental Protection Agency, as well as by state and local governments and governmental authorities in those foreign countries in which we or our partners operate.

Noncompliance with applicable regulatory policies or requirements of the FDA or other governmental authorities could subject us to enforcement actions, such as suspensions of product distribution, seizure of products, product recalls, civil monetary and other penalties, criminal prosecution and penalties, injunctions, whistleblower lawsuits, failure to approve pending drug product applications or total or partial suspension of product marketing approvals. Similar civil or criminal penalties could be imposed by other government agencies or the agencies of the states and localities in which our products are manufactured, sold or distributed, and could have ramifications for our contracts with government agencies. These enforcement actions would detract from management's ability to focus on our daily business and would have an adverse effect on the way we conduct our daily business, which could severely impact future profitability.

#### *Product Approval*

For innovative, or non-generic, new drugs, an FDA-approved new drug application, or NDA, is required before the drugs may be marketed in the United States. The NDA must contain data to demonstrate that the drug is safe and effective for its labeled uses, and that it will be manufactured to appropriate quality standards. In order to demonstrate safety and effectiveness, an NDA typically must include or reference preclinical data from animal and laboratory testing and clinical data from controlled trials in humans. For a new chemical entity, this generally means that lengthy, uncertain and rigorous pre-clinical and clinical testing must be conducted. For compounds that have a record of prior or current use, it may be possible to utilize existing data or medical literature and limited new testing to support an NDA. Any preclinical laboratory and animal testing must comply with FDA's good laboratory practice and other requirements. Clinical testing in human subjects must be conducted in accordance with FDA's good clinical practice and other requirements. In order to initiate a clinical trial, the sponsor must submit an investigational new drug application, or IND, to the FDA or meet one of the narrow exemptions that exist from the IND requirement. Clinical research must also be reviewed and approved by independent institutional review boards, or IRBs, at the sites where the research will take place, and the study subjects must provide informed consent. The FDA also regulates and typically inspects manufacturing facilities, equipment and processes used in the manufacturing of pharmaceutical products before granting approval to market any drug. Each NDA submission requires a substantial user fee payment, unless a waiver or exemption applies. FDA has committed generally to review and make a decision concerning approval on an NDA within 10 months, and on a new priority drug within six months. However, final FDA action on the NDA can take substantially longer, and where novel issues are presented there may be review and recommendation by an independent FDA advisory committee. The FDA can also refuse to file and review an NDA it deems incomplete or not properly reviewable.

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Clinical trial programs in humans generally follow a three-phase process. Typically, Phase I studies are conducted in small numbers of healthy volunteers or, on occasion, in patients afflicted with the target disease, to determine the metabolic and pharmacological action of the product candidate in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness. In Phase II, studies are generally conducted in larger groups of patients having the target disease or condition in order to validate clinical endpoints, and to obtain preliminary data on the effectiveness of the product candidate and optimal dosing. This phase also helps determine further the safety profile of the product candidate. In Phase III, large-scale clinical trials are generally conducted in hundreds of patients having the target disease or condition to provide sufficient data for the statistical proof of effectiveness and safety of the product candidate as required by U.S. and foreign regulatory agencies.

The FDA can, and does, reject new drug applications, require additional clinical trials, grant approvals on only a restricted basis even when product candidates performed well in clinical trials, or require further studies as a condition of approval. In addition, the Food and Drug Administration Amendments Act of 2007 (FDAAA) permits the agency to require new drug applicants to submit a risk evaluation and mitigation strategy (REMS) if the agency determines that a REMS is necessary to ensure that the benefits of the drug outweigh the risks.

Generic drugs are approved through an abbreviated process based on the submission to FDA of an abbreviated new drug application, or ANDA. The ANDA must seek approval of a drug product that has the same active ingredient(s), dosage form, strength, route of administration, and labeling as a so-called reference listed drug approved under an NDA, although some limited exceptions may be permitted. The ANDA also generally contains limited clinical data to demonstrate that the product covered by the ANDA is absorbed in the body at the same rate and to the same extent as the reference listed drug. This is known as bioequivalence. In addition, the ANDA must contain information regarding the manufacturing processes and facilities that will be used to ensure product quality, and must contain certifications to patents listed with the FDA for the reference listed drug. Special procedures apply when an ANDA contains certifications stating that a listed patent is invalid or not infringed, and if the owner of the patent or the NDA for the reference listed drug brings a patent infringement suit within a specified time, an automatic stay bars FDA approval of the ANDA for a specified period of time pending resolution of the suit or other action by the court. The amount of testing and effort that is required to prepare and submit an ANDA is generally substantially less than that required for an NDA.

In addition to the NDA and ANDA procedures, there is an additional approval mechanism known as a 505(b)(2) application. A 505(b)(2) application is a form of an NDA where the applicant does not have a right to reference all or some of the data being relied upon for approval. Under current regulations and FDA policies, 505(b)(2) applications can be used where the applicant is relying in part on published literature or on findings of safety or effectiveness in another company's NDA. This might be done, for example, where the applicant is seeking approval for a new use for a drug that has already been approved for a different use or for a different formulation of the same drug that is already approved for the same use.

The use of 505(b)(2) applications is the subject of ongoing legal controversy, and it is thus not clear what the permitted use of a 505(b)(2) application might be in the future.

In European Union countries (where our partner, Menarini is currently attempting to gain marketing approval for certain indications of FACTIVE) and in Canada, regulatory requirements and approval processes are similar in principle to those in the United States and can be at least as rigorous, costly and uncertain. Additionally, depending on the type of drug for which an applicant is requesting approval, there are currently two potential tracks for marketing approval in European Union countries: the centralized procedure and a de-centralized process which requires requesting approval on a country-by-country basis. These review mechanisms may ultimately lead to approval in all European Union countries, but each method grants all participating countries some decision making authority in product approval.

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### *Post-Approval Requirements*

Products on the market are subject to continual review by the FDA. If previously unknown problems are discovered or if there is a failure to comply with applicable regulatory requirements, the FDA may restrict the marketing of an approved product, cause the withdrawal of the product from the market, or under certain circumstances seek recalls, seizures, injunctions or criminal sanctions. For example, the FDA may require a change in labeling for an approved marketing application or additional studies for any marketed drug product if new information reveals questions about a drug's safety or effectiveness. In addition, changes to the product, the manufacturing methods or locations, or labeling are subject to additional FDA approval, which may or may not be received, and which may be subject to a lengthy FDA review process.

Manufacturing facilities that produce drugs are subject to extensive regulation both by the FDA, state and local governments, and foreign regulatory authorities. These laws and regulations require, among other things, that our facilities and the facilities of third parties, such as LG Life Sciences, Ethypharm S.A., Patheon Pharmaceuticals Inc. (our third party finished-product manufacturer for FACTIVE tablets) and Catalent Pharma Solutions (our third party packager of ANTARA capsules), be registered with the FDA and other regulatory authorities, comply with current good manufacturing practices requirements, and pass periodic inspections by the FDA and other regulators. 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, injunctions or recall of product and fines and other penalties. Compliance with these requirements can be time consuming, costly and can result in delays in product approval or product sales.

In addition to cGMP requirements, certain of our products must also be packaged with child-resistant and senior friendly packaging under the Poison Prevention Packaging Act and Consumer Product Safety Commission regulations. Products that do not comply with these requirements can be considered misbranded and subject to seizure, recall, monetary fines, and other penalties.

The distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. States require the registration of manufacturers and distributors who provide pharmaceuticals, including in certain states even if these manufacturers or distributors have no place of business within the state but satisfy other nexus requirements, for example, the shipment of products into such state. States also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that are requiring manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Both the PDMA and state laws limit the distribution of prescription drug product samples to licensed practitioners and impose other requirements to ensure accountability in the distribution of samples.

Other reporting and recordkeeping requirements also apply for marketed drugs, including for most products requirements to review and report cases of adverse events. Product advertising and promotion are subject to FDA and state regulation, including requirements that promotional claims conform to any applicable FDA approval, and be appropriately balanced and substantiated. We are also subject to various federal and state laws pertaining to health care fraud and abuse, including the anti-kickback provisions of the Social Security Act, the False Claims Act, the Veterans Healthcare Act, and the implementing regulations and policies of the United States Health and Human Services Office of Inspector General and United States Department of Justice, as well as similar state laws. Anti-kickback laws make it illegal for a prescription drug manufacturer or marketer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase, recommendation or prescription of a particular drug, covered by a federal healthcare program, unless

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one of several narrow safe harbors or other exceptions applies. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented, for payment to third-party government payors, including Medicare and Medicaid, claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services.

Similar laws apply in other countries, including anti-bribery prohibitions in the European Union and member countries of the European Union.

### *Other Regulatory and Compliance Requirements*

Under the laws of the United States, the countries of the European Union and other nations, we and the institutions where we sponsor research are subject to obligations to ensure the protection of personal information of human subjects participating in our clinical trials. In the United States, these laws include the privacy provisions of the Health Insurance Portability and Accountability Act, or HIPAA, the implementing regulations of the United States Department of Health and Human Services, and state medical records privacy laws. We have instituted procedures that we believe will enable us to comply with these requirements and the contractual requirements of our data sources. The laws and regulations in this area are evolving and further regulation, if adopted, could affect the timing and the cost of future clinical development activities.

We are subject to the United States Foreign Corrupt Practices Act, which prohibits corporations and individuals from engaging in specified activities to obtain or retain business or to influence a person working in an official capacity. Under this act, it is illegal to pay, offer to pay, or authorize the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. Our present and future business has been and will continue to be subject to various other laws and regulations.

### *Pricing and Third-Party Reimbursement*

In the United States and elsewhere, sales of therapeutic and other pharmaceutical products are dependent in part on the availability of reimbursement to the consumer from third party payors, such as government and private insurance plans. Increasingly, third party payors are challenging the prices charged for medical products and services. As a result, in the future, our products could be considered not cost effective or reimbursement to the consumer could become unavailable or could be insufficient to allow us to sell our products on a competitive and profitable basis. For example, in some foreign markets, pricing reimbursement or profitability of therapeutic and other pharmaceutical products is subject to governmental control. In Canada this practice has led to lower priced products than in the United States. As a result, importation of products from Canada into the United States may result in reduced product revenues. In the United States there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental pricing reimbursement controls. For example, Congress may give the federal government authority to negotiate drug prices for the Medicare Part D outpatient prescription drug benefit. Currently under Part D, prices are negotiated by the manufacturer with individual Part D plan sponsors or their administrators. Medicare Part B provides separate reimbursement for a limited universe of prescription drugs (primarily physician administered drugs). Currently, reimbursement for most Part B drugs is set at 106% of average sales price (which a manufacturer must report quarterly). Congress may consider proposals to reduce reimbursement for Part B drugs.

In many foreign markets, including the countries in the European Union, pricing of pharmaceutical products is subject to governmental control. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental pricing controls. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and results.

Through the commercialization of ANTARA and FACTIVE, we became a participant in the Medicaid rebate program established by the Omnibus Budget Reconciliation Act of 1990, and most recently amended

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under the Deficit Reduction Act of 2005. Under the Medicaid rebate program, we pay a rebate for each unit of our product reimbursed by Medicaid. The amount of the rebate for each product is set by law as a minimum of 15.1% of the average manufacturer price, or AMP, of that product, or if it is greater, the difference between AMP and the best price available from us to any commercial customer. The rebate amount also includes an inflation adjustment if AMP increases faster than inflation. The rebate amount is recomputed each quarter based on our reports of our current average manufacturer price and best price for each of our products to the Centers for Medicare & Medicaid Services, or CMS. In order to meet the requirements of the Deficit Reduction Act of 2005, these prices must now be reported to CMS monthly in addition to quarterly.

Participation in the Medicaid rebate program requires participation in the Public Health Service, or PHS, pharmaceutical pricing program. The PHS pricing program extends discounts comparable to the Medicaid rebate to a variety of community health clinics and other entities that receive health services grants from the PHS, as well as hospitals that serve a disproportionate share of low-income Medicare and Medicaid beneficiaries.

ANTARA and FACTIVE are available to authorized users of the Federal Supply Schedule of the General Services Administration. Since 1993, as a result of the Veterans Health Care Act of 1992, or VHC Act, federal law has required that product prices for purchases by the Veterans Administration, the Department of Defense, Coast Guard, and the PHS, including the Indian Health Service, be discounted by a minimum of 24% off the non-federal average manufacturer price, or non-FAMP. Our computation and report of non-FAMP is used in establishing the price, and the accuracy of the reported non-FAMP may be audited by the government under applicable federal procurement laws.

## **PATENTS AND PROPRIETARY TECHNOLOGY**

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 55 issued U.S. patents, approximately 57 pending U.S. patent applications, approximately 58 issued foreign patents and approximately 111 pending foreign patent applications. These patents and patent applications primarily relate to (1) the chemical composition, use, and method of manufacturing FACTIVE, (2) pharmaceutical compositions, methods of their use and treatment, and methods of manufacturing ANTARA, (3) metalloenzyme inhibitors, their uses and their targets, (4) anti-infective compounds and their uses, and (5) 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-methoxyiminopyrrolidin-1-yl)-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1, 8-naphthyridine-3-carboxylic acid; licensed from LG Life Sciences; expiring April 4, 2017;

U.S. Patent No. 5,869,670 granted February 9, 1999, relating to 7-(4-aminomethyl-3-methoxyiminopyrrolidin-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-methoxyiminopyrrolidin-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;





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

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

U.S. Patent No. 6,723,734 granted April 20, 2004, relating to the salt of naphthyridine carboxylic acid derivative; licensed from LG Life Sciences; expiring March 20, 2018;

U.S. Patent No. 6,803,376 granted October 12, 2004, relating to methods of use of quinolone compounds against pneumococcal pathogenic bacteria; licensed from LG Life Sciences; expiring September 21, 2019;

U.S. Patent No. 7,101,574 granted September 5, 2006, relating to pharmaceutical compositions containing fenofibrate and methods of preparing the same; licensed from Ethypharm, S.A.; expiring August 20, 2020; and

U.S. Patent No. 7,317,001 granted January 8, 2008, relating to methods of use of Ramoplanin for the treatment of *Clostridium difficile*-Associated Disease (CDAD); expiring December 20, 2024.

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 development, license and supply agreement with Ethypharm, S.A., we assumed all of the rights and obligations related to the development, manufacturing, marketing and sale of ANTARA in the United States. This license includes one issued U.S. patent and several pending patent applications. In conjunction with the financing of our acquisition of ANTARA, we entered into a Security Agreement with Paul Royalty Fund Holdings II, LP, an affiliate of Paul Capital Partners, or Paul Capital, under which our wholly-owned subsidiary, Guardian II Acquisition Corporation granted Paul Capital a security interest in all of its assets, including all rights to ANTARA intellectual property, in order to secure its performance under the financing agreements with Paul Capital. These patents and applications include claims that relate to pharmaceutical compositions containing fenofibrate using the drug delivery technologies incorporated in ANTARA, methods of their use and treatment, and methods of preparing the same. The patent issued to Ethypharm which is listed in the FDA Orange Book is set to expire in 2020.

Under our license agreement with LG Life Sciences, we obtained an exclusive license to develop and market gemifloxacin in certain territories. This license covers 16 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. We have received a Notice of Final Determination from the U.S. Patent and Trademark Office on our patent term extension application for U.S. Patent No. 5,776,944 extending its patent term 659 days to April 4, 2017. The principal U.S. patents are currently set to expire at various dates, ranging from 2015 to 2019.

The patents relating to Ramoplanin include claims relating to methods of manufacturing Ramoplanin as well as methods of increasing the yield of the active compound. On January 8, 2008, the United States Patent and Trademark Office (USPTO) issued us a U.S. patent relating to methods of use of Ramoplanin for the treatment of *Clostridium difficile*-associated disease, or CDAD. We also have applications pending relating to various novel uses of Ramoplanin as well as a formulation containing Ramoplanin. The patent covering the chemical

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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 we believe we would receive under the Hatch-Waxman Act in the U.S. and the ten years of market exclusivity in Europe available through the European Medicines Agency (EMA), because Ramoplanin would be a new chemical entity not previously marketed commercially.

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. We acquired exclusive rights to ANTARA trademarks, trade names, domain names and logos. After becoming aware that Antara Biosciences, Inc. filed trademark applications with the USPTO for the ANTARA and ANTARA BIOSCIENCES marks in connection with biotechnology related goods and services we filed a complaint in Federal District Court alleging, among other things, trademark infringement seeking to enjoin ANTARA BIOSCIENCES from using the ANTARA mark. We have reached a settlement with ANTARA BIOSCIENCES whereby they have agreed to abandon their ANTARA trademark applications and cease using the ANTARA marks. Accordingly we have dismissed our complaint before the Federal District Court.

We also rely upon 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.

## **MANUFACTURING**

Currently, our source of supply of bulk capsules of ANTARA is Ethypharm, S.A, which produces the capsules at its facilities in France. Ethypharm is able to receive ANTARA API from two vendors in Spain and Italy. We also have an agreement with Catalent Pharma Solutions (formerly Cardinal Health) to package finished ANTARA capsules.

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 API. LG Life Sciences supplies the FACTIVE API from its manufacturing facility in South Korea. Patheon Pharmaceuticals Inc. currently manufactures the finished tablets. With respect to our sublicense of commercialization rights to FACTIVE in ex-US territories:

Pfizer Mexico must purchase all of its commercial requirements in Mexico for FACTIVE API from us, but has the option to receive FACTIVE product from us or to fill and finish the final tableted FACTIVE product at its manufacturing facilities in Mexico. We have transferred the required technology to Pfizer Mexico so that it can start its fill and finish activities;

Abbott Canada must purchase its commercial requirements for Canada of FACTIVE finished product from us;

With respect to the anticipated commercialization of FACTIVE in Europe, Menarini must purchase all of its requirements for FACTIVE active pharmaceutical ingredient from us, but may request that we supply finished FACTIVE product to it for an interim period of time while the technology transfer process is completed.

Pursuant to our acquisition of worldwide rights to Ramoplanin from Pfizer (formerly Vicuron), we are responsible for the manufacture of both the active pharmaceutical ingredient and finished dosage form of

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Ramoplanin. Although we plan to seek a partner for Ramoplanin, a contract manufacturer or the partner would be required to produce both the active pharmaceutical ingredient and the final dosage form to support related manufacturing activities.

**HUMAN RESOURCES**

As of December 31, 2007, we had 322 full-time equivalent employees. None of our employees are covered by a collective bargaining agreement, and we consider our relations with our employees to be good.

**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 such 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**

The following are significant factors known to us that could materially adversely affect our business, financial condition, or operating results. The risks described below are not the only risks facing us. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

#### **RISKS RELATED TO OUR BUSINESS**

##### **We have a history of significant operating losses and expect losses to continue for some time.**

We have a history of significant operating losses and expect losses to continue for some time. Although we recorded a one-time, non-cash gain of approximately \$30,824,000 in the second quarter related to the convertible debt exchange, we expect to continue to have net losses in the near future and we had an accumulated deficit of approximately \$445,758,000 as of December 31, 2007. These losses are primarily a result of costs incurred in research and development, including our clinical trials and product acquisitions, from sales and marketing, and from general and administrative costs associated with our operations and product sales. These costs have exceeded our revenues which to date have been generated principally from sales of ANTARA and FACTIVE, co-promotion revenues based on the sale of TESTIM<sup>®</sup> gel (which we no longer promote), sublicensing agreements, and our legacy collaborations, government grants and sequencing services.

We anticipate that we will incur additional losses in the current year and in future years. These losses are expected to continue, principally due to the expenses in the sales and marketing area, as we seek to grow sales of ANTARA capsules and FACTIVE tablets and as we seek to acquire additional approved products or product candidates. Additionally, our partners' product development efforts that 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 is very dependent on the commercial success of ANTARA and FACTIVE.**

ANTARA capsules and FACTIVE tablets 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 or until we successfully acquire, in-license or enter into co-promotion agreements for additional products.

ANTARA is approved by the FDA to treat hypercholesterolemia (high blood cholesterol) and hypertriglyceridemia (high triglycerides) in combination with a healthy diet. FACTIVE tablets have FDA marketing approval for the treatment of community-acquired pneumonia of mild to moderate severity, or CAP, and acute bacterial exacerbations of chronic bronchitis, or AECB. The commercial success of ANTARA and FACTIVE 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 hypercholesterolemia and hypertriglyceridemia, in the case of ANTARA capsules. In addition, if concerns should arise about the safety or efficacy of our products, regardless of whether or not such concerns have a basis in generally accepted science or peer-reviewed scientific research, such concerns could adversely affect the market for these products. If ANTARA and FACTIVE are not commercially successful, we will have to find additional sources of funding or curtail or cease operations.

##### **If third parties challenge the validity of the patents or proprietary rights of our marketed products or assert that we have infringed their patents or proprietary rights, we may become involved in intellectual property disputes and litigation that would be costly, time consuming, and prevent the commercialization of ANTARA, FACTIVE and/or any other products that we acquire.**

The intellectual property rights of pharmaceutical companies, including us, are generally uncertain and involve complex legal, scientific and factual questions. Our success in developing and commercializing

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pharmaceutical products may depend, in part, on our ability to operate without infringing on the intellectual property rights of others and to prevent others from infringing on our intellectual property rights. There has been substantial litigation regarding patents and other intellectual property rights in the pharmaceutical industry. For example, third parties seeking to market generic versions of branded pharmaceutical products often file an Abbreviated New Drug Application ( ANDA ) with the FDA, wherein such ANDA contains a certification by the applicant that the patents protecting the branded pharmaceutical product are invalid, unenforceable and/or not infringed, a so-called Paragraph IV certification. As described under, Our products and product candidates face significant competition in the marketplace, Teva recently filed such an ANDA containing a Paragraph IV certification with the FDA seeking the approval of a generic version of Tricor 145 mg. If such a filing is made referencing either ANTARA or FACTIVE, we may need to defend and/or assert our patents, including filing lawsuits alleging patent infringement which would be extremely costly to us. If we were unsuccessful in such a proceeding and the FDA approved a generic version of any one or both of our products, such an outcome would have a material adverse effect on our business.

We may also 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 pharmaceutical 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. 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 and be liable for damages. In certain cases, a license may be available, although we may not be able to obtain such a license on commercially acceptable terms, or at all.

We are aware of United States patents that are controlled by third parties that may be construed to encompass ANTARA. However, we believe that, if these patents were asserted against us, we would have valid defenses that ANTARA does not infringe any valid claims of these patents or that the patents would be found to be unenforceable. Nonetheless, in order to successfully challenge the validity of any United States patent, we would need to overcome the presumption of validity which is accorded to issued patents in the United States. If any of these patents were found to be valid and enforceable and we were found to infringe any of them, or any other patent rights of third parties, we would be required to pay damages, cease the sale of ANTARA or pay additional royalties on manufacture and sales of ANTARA. If we are unable to market or sell ANTARA, or if we are obligated to pay significant damages or additional royalties, our earnings attributable to ANTARA would be reduced and our business would be materially adversely affected. Even if we prevail, the cost to us of any patent litigation would likely be substantial, and it may absorb significant management time. If the other party in any such litigation has substantially greater resources than us, we may be forced, due to cost constraints, to seek to settle any such litigation on terms less favorable to us than we might be able to obtain if we had greater resources.

**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, 2007, we had approximately \$303.9 million of indebtedness outstanding (including accrued interest and excluding a bond discount of approximately \$43.1 million), which includes approximately \$41.2 million in revenue interest that entitles Paul Capital to receive a royalty on the sales of both ANTARA and FACTIVE. Approximately \$17.2 million of outstanding indebtedness will mature in 2009, approximately \$22.0 million of outstanding indebtedness will mature in 2010 or it may be extended at our option to 2012 through issuance of warrants and approximately \$223.5 million of indebtedness will mature in 2011. Included in the above is the exchange offer completed on May 1, 2007 relating to the

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existing convertible debt and a new debt offering of \$60 million which generated net proceeds to the Company of approximately \$40.4 million. The level and nature of our indebtedness, among other things, could:

make it difficult for us to make payments on our debt outstanding from time to time or to refinance it;

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;

place us at a possible competitive disadvantage relative to less leveraged competitors and competitors that have better access to capital resources;

restrict the operations of our business as a result of provisions in the Revenue Interests Agreement with Paul Capital that restrict our ability to (i) amend, waive any rights under, or terminate any material license agreements, including the agreements relating to the ANTARA products and FACTIVE, (ii) enter into any new agreement or amend or fail to exercise any of our material rights under existing agreements that would materially adversely affect Paul Capital's royalty interest, and (iii) sell any material assets related to ANTARA or FACTIVE; or

impair our ability to merge or otherwise effect the sale of the Company due to the right of the holders of certain of our indebtedness to accelerate the maturity date of the indebtedness in the event of a change of control of the company.

If we do not grow our revenues as we expect, 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 would have a material adverse effect on our business, operating results and financial condition.

**We may need to raise additional funds in the future.**

We believe our existing funds, including approximately \$40.4 million we received as a result of the completion of our convertible debt offering in May 2007, and anticipated cash generated from operations should be sufficient to support our current plans through at least the end of 2008. We may need to raise additional capital in the future to fund our operations and/or other potential commercial or development opportunities, to support our sales and marketing activities, and to fund clinical trials and other research and development activities. We may seek funding through additional public or private equity offerings, debt or other strategic financings or agreements with customers or vendors. Our ability to raise additional capital, however, will be impacted by, among other factors, the investment market for pharmaceutical companies and the progress of the ANTARA and FACTIVE commercial programs, our ability to acquire, in-license or enter into co-promotion agreements for additional products, our progress in finding a development and commercialization partner for Ramoplanin and our progress with other business development transactions. 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 fundraising could dilute the ownership interests of our shareholders.**

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

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significant percentage of the outstanding shares of our common stock in order to fund our operating plans, potentially requiring a shareholder vote. In addition, we may have to sell securities at a discount to the prevailing market price, resulting in further dilution to our shareholders.

### **We need to continue to develop marketing and sales capabilities to successfully commercialize ANTARA capsules, FACTIVE tablets and our other product candidates.**

ANTARA capsules and FACTIVE tablets are the first two FDA-approved products which we own and promote. To date, we still have limited marketing and sales experience. The continued development of these marketing and sales capabilities, including any expansion of our sales force, will require significant expenditures, management resources and time. Failure to establish sufficient sales and marketing capabilities in a timely and regulatory compliant manner may adversely affect our ability to assume and continue to grow the ANTARA and FACTIVE brands and related product sales.

### **Our products and product candidates face significant competition in the marketplace.**

#### *ANTARA*

ANTARA is a fenofibrate product approved by the FDA to treat hypercholesterolemia and hypertriglyceridemia in combination with a healthy diet. The marketing of current and additional branded versions of fenofibrate could reduce our net sales of ANTARA and adversely impact our revenues. The primary competition for ANTARA in the fenofibrate market is Tricor 145 mg, a product manufactured by Abbott Laboratories, which accounted for approximately 92% of U.S. fenofibrate sales for the year ended December 31, 2007. Abbott has announced its development and evaluation of another branded fenofibrate-type product, both as mono and combination therapy.

In addition to Tricor, there are several other branded fenofibrate products which compete with ANTARA. ANTARA also competes with Triglide, a 160 mg fenofibrate product marketed by Sciele Pharma, Inc., which accounted for approximately 2% of U.S. fenofibrate sales for the year ended December 31, 2007. Additionally, ANTARA competes with Lipofen, a 150 mg fenofibrate product, which was recently launched and is currently being marketed by ProEthic Pharmaceuticals, Inc. LifeCycle Pharma A/S recently announced the FDA approval of their 120 mg branded fenofibrate product, which had been filed with the FDA in late 2006 referencing ANTARA in accordance with the provisions of section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act. LifeCycle Pharma granted Sciele Pharmaceuticals rights to market its fenofibrate product in North America, which when launched can also be expected to compete with ANTARA.

Additionally, several generic versions of fenofibrate in varying doses are also available for the treatment of dyslipidemias. Revenues from these products accounted for approximately 2% of total U.S. sales of fenofibrate sales in 2007. In May 2005, Teva Pharmaceutical Industries, Ltd. (Teva) obtained FDA approval to market a generic version of Abbott Laboratories' 160 mg Tricor tablet (which is no longer marketed or sold). In addition, Solvay S.A., Abbott Laboratories' partner announced on January 23, 2008, that Teva had filed an Abbreviated New Drug Application (ANDA) with a Paragraph IV certification seeking the approval of a generic version of Tricor 145 mg. If a generic version of Abbott Laboratories' Tricor 145 mg product is approved by the FDA, the percentage of total revenues attributable to generic fenofibrate products would likely increase. There are also several other FDA-approved products and products in development for similar indications as ANTARA which could compete with ANTARA, including statins, omega-3 fatty acids, niacin, ezetimibe and fixed-dose, combination products.

The growth of any of these competitive branded products, the marketing of generic fenofibrate products or the FDA approval and subsequent marketing of products with similar indications including combination therapy products currently in development could result in a decrease in ANTARA sales, pressure on the price at which we are able to sell ANTARA, reduce our profit margins, reduce our net sales of ANTARA and adversely impact our revenues.



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*FACTIVE*

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 (levofloxacin, ciprofloxacin and moxifloxacin), macrolides (clarithromycin and azithromycin), cephalosporins (cefdinir) and penicillins (amoxicillin/clavulanate potassium).

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 composition of matter patents which have expired or will expire at dates ranging from 2003 to 2016. 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.

*Ramoplanin*

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 pulvules (vancomycin), a product marketed by ViroPharma Inc., and metronidazole, a generic product, for treatment of this indication. We are also aware of several companies with products in development for the treatment of CDAD as well as the potential for generic vancomycin.

Many of our competitors have substantially greater capital resources 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.

**Our failure to in-license, co-promote or 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 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 up-front cash payments, which could adversely affect our liquidity and/or may require us to raise additional capital and/or secure external sources of financing. We may seek funding for product acquisitions through equity or debt offerings, through royalty-based financings or by a combination of these methods, such as the financing we completed with Paul Capital to fund the ANTARA acquisition. There is no assurance that we will be able to raise the funds necessary to complete any product acquisitions on acceptable terms or at all. If we raise funds it could dilute shareholders, or if we use existing resources it could adversely affect our liquidity and 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,

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effective or approved by regulatory authorities. In addition, it is uncertain whether any approved products that we develop or acquire will be:

manufactured or produced economically;

successfully commercialized; or

widely accepted in the marketplace.

**We, 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.**

Virtually all aspects of our and our partners' activities are subject to regulation by numerous governmental authorities in the U.S., Europe, Canada, Mexico and elsewhere. These regulations govern or affect the testing, manufacture, safety, effectiveness, labeling, storage, record-keeping, approval, distribution, advertising and promotion of ANTARA, FACTIVE, Ramoplanin and our other product candidates, as well as safe working conditions and the experimental use of animals. We are required to report any serious and unexpected adverse experiences with our products to the FDA and other similar regulatory authorities in other jurisdictions. Noncompliance with any applicable regulatory requirements or failure to obtain adequate documentation from any governmental agency can result in refusal of the government to approve products for marketing, criminal prosecution and fines, recall or seizure of products, injunctions, total or partial suspension of production, whistleblower lawsuits, prohibitions or limitations on the commercial sale of products or refusal to allow the entering into of federal and state supply contracts. These enforcement actions would detract from management's ability to focus on our daily business and would have an adverse effect on the way we conduct our daily business, which could severely impact future profitability. Our corporate compliance program cannot fully 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.

For instance, we, along with many other pharmaceutical companies, received correspondence in 2007 from the FDA stating that it had some concerns over the reliability of studies conducted by MDS Pharma Services between 2000 and 2004. The predecessor owner of the rights to ANTARA, Reliant Pharmaceuticals, had engaged MDS Pharma to perform certain bioequivalence studies for ANTARA, including some studies that were submitted in support of the original approval of ANTARA. The FDA suggested that we take one of the following steps to assess the accuracy of such data: conduct an independent audit of the trials to verify the data, re-assay samples or repeat the studies. The FDA also stated that it has not detected any signals or any evidence that the products mentioned in its correspondence pose a safety risk or that there has been any impact on efficacy. We have responded to the FDA informing the FDA that we do not believe that these steps are necessary because the FDA audited the pivotal MDS Pharma study at issue prior to its approval of ANTARA, and further because there are other non-MDS Pharma data that support the safety and effectiveness of ANTARA. Because the outcome of this issue is uncertain, we cannot predict whether this issue will have a material impact on our results of operations.

**New legal and regulatory requirements could make it more difficult for us to obtain expanded or new product approvals, and could limit or make more burdensome our ability to commercialize our approved products.**

Numerous proposals have been made in recent years to impose new requirements on drug approvals, expand post-approval requirements, and restrict sales and promotional activities. Without limiting the generality of the foregoing, Congress has recently enacted, and the President has signed into law, the Food and Drug Administration Amendments Act of 2007 (FDAAA). The recently enacted amendments would among other things, require all new drug applicants to submit risk evaluation and minimization plans to monitor and address potential safety issues for products upon approval, grant the FDA the authority to impose risk management measures for marketed products and to mandate labeling changes in certain circumstances, and establish new

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requirements for disclosing the results of clinical trials. Additional measures have also been enacted to address the perceived shortcomings in the FDA's handling of drug safety issues, and to limit pharmaceutical company sales and promotional practices. The implementation of the recently enacted amendments or other proposed legal or regulatory changes may make it more difficult or burdensome for us to obtain extended or new product approvals, and our current approvals may be restricted or subject to onerous post-approval requirements. Such changes may increase our costs and adversely affect our operations. The ability of us or our partners to commercialize approved products successfully may be hindered, and our business may be harmed as a result.

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

restrictions on our products or manufacturing processes;

notice of violation letters regarding promotional and marketing materials and activities;

withdrawal of the product from the market;

voluntary or mandatory recall of the product;

fines against us or our partners;

suspension or withdrawal of regulatory approvals for ANTARA, FACTIVE or a product candidate which subsequently receives regulatory approval;

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.

**If we market or distribute products in a manner that violates federal or state healthcare fraud and abuse, marketing disclosure or drug pedigree laws, we may be subject to civil or criminal penalties.**

In addition to FDA and related regulatory requirements, we are subject to health care fraud and abuse laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback

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laws prohibit, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally or state financed health care programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, patients, purchasers and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing, or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for

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uses that the FDA has not approved, or off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses; and submitting inflated best price information to the Medicaid Rebate Program.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would also harm our financial condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

In recent years, several states and localities, including California, the District of Columbia, Maine, Minnesota, Nevada, New Mexico, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, and file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar legislation is being considered in other states. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. We are not aware of any companies against which fines or penalties have been assessed under these special state reporting and disclosure laws to date. Nonetheless, while we have established a compliance program, we may face enforcement, fines and other penalties, and could receive adverse publicity if this program is found not to be in full compliance with these laws.

In recent years, some states have passed or have proposed laws and regulations obligating pharmaceutical manufacturers and distributors to provide prescription drug pedigrees that are intended to protect the safety of the supply channel. For example, the Florida Prescription Drug Pedigree laws and regulations that became effective in July 2006 imposed obligations upon us to deliver prescription drug pedigrees to various categories of customers. Also, effective January 1, 2009, California will require the implementation of costly track and trace chain of custody technologies. At the federal level, the FDA issued final regulations pursuant to the Pharmaceutical Drug Marketing Act that became effective in December 2006. Compliance with these pedigree laws requires implementation of extensive tracking systems as well as heightened documentation and coordination with distributors and customers. While we fully intend to comply with these laws, there is uncertainty around the interpretation of the recently passed laws, future changes in legislation and government enforcement of these laws. Failure to comply could result in fines or penalties, as well as loss of business that could have a material adverse effect on our business.

### **We depend on third parties to manufacture and distribute our products and product candidates.**

We do not have the internal capability to manufacture pharmaceutical products. Under our agreement with LG Life Sciences, LG Life Sciences manufactures the API of FACTIVE and is our only source of supply. We use Patheon Inc. (Patheon) to produce the finished FACTIVE tablets and it is currently our only source of supply of bulk capsules of ANTARA is Ethypharm which manufactures the bulk capsules in France and is able to receive ANTARA API from two vendors in Spain and Italy. Further, we have an agreement with Catalent Pharma Solutions, Inc. to package finished ANTARA capsules and FACTIVE tablets.

If Ethypharm, LG Life Sciences, Patheon or Catalent Pharma Solutions experiences any significant difficulties in their respective manufacturing processes for our products including the API or finished product, we could experience significant interruptions in the supply of ANTARA and FACTIVE. Our inability to coordinate the efforts of our third party manufacturing partners, or the lack of capacity available at our third party manufacturing partners, could impair our ability to supply ANTARA and FACTIVE at required levels. Such an

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interruption could cause us to incur substantial costs and our ability to generate revenue from ANTARA and FACTIVE may be adversely affected. 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 manufactured by the new source or from the modified process is equivalent to the product used in any clinical trials that we had conducted. Due to these regulatory requirements, we could experience significant interruptions in the supply of ANTARA and FACTIVE if we decided to transfer the manufacture of our products to one or more suppliers in an effort to deal with such difficulties.

As the ANTARA bulk capsules and FACTIVE API are manufactured in France and South Korea, respectively, we must ship our products to the United States for finishing, packaging and labeling, and manufacturing in the case for FACTIVE. While in transit, our API and product, each shipment of which is of significant value, could be lost or damaged. Moreover, at any time after shipment to the United States, our API or finished product could be lost or damaged as our FACTIVE API is stored at Patheon and our ANTARA and FACTIVE finished product is stored at our third party logistics provider, Integrated Commercialization Solutions, Inc. (ICS). Appropriate risk mitigation steps have been taken and insurance is in place. However, depending on when in the process the API or finished product is lost or damaged, we may have limited recourse for recovery against our manufacturers or insurers. As a result, our financial performance could be impacted by any such loss or damage to our API or finished product.

We may also experience interruption or significant delay in the supply of ANTARA and FACTIVE due to natural disasters, acts of war or terrorism, shipping embargoes, labor unrest or political instability in France or South Korea. In any such event, the supply of our products stored at Ethypharm or LG Life Sciences could also be impacted.

Pursuant to our acquisition of worldwide rights to Ramoplanin from Pfizer (formerly Vicuron), we are responsible for the manufacture of both the active pharmaceutical ingredient and finished dosage form of Ramoplanin. Although we plan to seek a partner for Ramoplanin, a contract manufacturer or the partner would be required to produce both the active pharmaceutical ingredient and the final dosage form to support related manufacturing activities. If there is a significant delay in securing a qualified supplier on commercially favorable terms, we could experience a supply shortage of Ramoplanin bulk drug, possibly affecting our ability to consummate partnering arrangements for the commercialization of Ramoplanin.

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.

### **We depend on third parties to assist in the management and execution of our product supply chain for ANTARA capsules and FACTIVE tablets.**

We do not have the internal capability to perform product supply chain services including warehousing, inventory management, storage and distribution of commercial and sample quantities of ANTARA capsules and FACTIVE tablets. We have an exclusive arrangement with Integrated Commercialization Solutions, Inc. (ICS) to perform such supply chain services with respect to commercial product through the second quarter of 2010.

We cannot be certain that ICS will be able to perform uninterrupted supply chain services. If ICS 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 ANTARA and FACTIVE, in addition to loss of sales, we may also incur costs in establishing a new arrangement.

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

We sell ANTARA and FACTIVE to wholesale drug distributors who generally sell products to retail pharmacies and other institutional customers. We do not promote ANTARA and FACTIVE to these wholesalers, and they do not determine such products prescription demand. However, approximately 89% of our product shipments during the year ended December 31, 2007 were to only three wholesalers. Our ability to commercialize ANTARA and/or FACTIVE will depend, in part, on the extent to which we maintain adequate distribution of ANTARA capsules and FACTIVE tablets via wholesalers, pharmacies and hospitals, as well as other customers. Although a majority of the larger wholesalers and retailers distribute and stock ANTARA and FACTIVE, 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 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 ANTARA capsules or FACTIVE tablets, the commercialization of ANTARA and/or FACTIVE and our anticipated revenues and results of operations could be adversely affected.

**Under our financing arrangement with Paul Capital, upon the occurrence of certain events, Paul Capital may require us to repurchase the right to receive revenues that we assigned to it or may foreclose on certain assets that secure our obligations to Paul Capital. Any exercise by Paul Capital of its right to cause us to repurchase the assigned right or any foreclosure by Paul Capital could adversely affect our results of operations and our financial condition.**

On August 18, 2006, we and our subsidiary Guardian II Acquisition Corporation, or Guardian II, entered into a revenue interests assignment agreement with Paul Capital pursuant to which we assigned to Paul Capital the right to receive a portion of our net revenues from FACTIVE tablets and Guardian II assigned to Paul Capital the right to receive a portion of its net revenue from ANTARA capsules. To secure its obligations to Paul Capital, Guardian II also granted Paul Capital a security interest in substantially all of its assets, including the U.S. rights to ANTARA.

Under our arrangement with Paul Capital, upon the occurrence of certain events, including if we experience a change of control, undergo certain bankruptcy events of us or our subsidiary, transfer any or substantially all of our rights in ANTARA or FACTIVE, transfer all or substantially all of our assets, breach certain of the covenants, representations or warranties under the revenue interests assignment agreement, or sales of ANTARA are suspended due to an injunction or if we elect to suspend sales of ANTARA as a result of a lawsuit filed by certain third parties, Paul Capital may (i) require us to repurchase the rights we assigned to it at the put/call price in effect on the date such right is exercised or (ii) foreclose on the ANTARA assets that secure our obligations to Paul Capital. Except in the case of certain bankruptcy events, if Paul Capital exercises its right to cause us to repurchase the rights we assigned to it, Paul Capital may not foreclose unless we fail to pay the put/call price as required.

If Paul Capital were to exercise its right to cause us to repurchase the right we assigned to it, we cannot assure you that we would have sufficient funds available to pay the put/call price in effect at that time. Even if we have sufficient funds available, we may have to use funds that we planned to use for other purposes and our results of operations and financial condition could be adversely affected. If Paul Capital were to foreclose on the ANTARA assets that secure our obligations to Paul Capital, our results of operations and financial condition could also be adversely affected. Paul Capital's right to cause us to repurchase the rights we assigned to it is triggered by, among other things, a change in control, transfer of any of our interests in ANTARA or transfer of all or substantially all of our assets, the existence of that right could discourage us or a potential acquirer from entering into a business transaction that would result in the occurrence of any of those events.

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**The development and commercialization of our products may be terminated or delayed, and the costs of development and commercialization may increase, if third parties upon whom we rely 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 do 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 have entered into exclusive arrangements granting rights to Pfizer, S.A. de C.V, Abbott Laboratories, Ltd. and Menarini International Operation Luxembourg SA to develop and sell FACTIVE in Mexico, Canada and Europe, respectively. However, we have recently amended our agreement with Abbott Canada whereby Abbott Canada's development and commercial obligations were substantially reduced.

We may not be able to maintain our existing arrangements with respect to the commercialization of our existing products, ANTARA and FACTIVE, or establish and maintain arrangements or partnerships 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, our other product candidates 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 ANTARA capsules, FACTIVE tablets, Ramoplanin, our other product candidates or any additional product candidates that we may acquire or develop;

require us to undertake unforeseen additional responsibilities or devote unforeseen additional resources to the development or commercialization of our products; or

result in the termination of the development or commercialization of our products.

**We bear substantial responsibilities under our license agreements for ANTARA and FACTIVE and our sublicense agreements to Pfizer, S.A. de C.V., Abbott Laboratories, Ltd. and Menarini International Operation Luxembourg SA, and there can be no assurance that we will successfully fulfill our responsibilities.**

*ANTARA*

Our exclusive rights to ANTARA are licensed to us by Ethypharm, S.A. (Ethypharm). If we breach the development, license and supply agreement with Ethypharm, it may be entitled to terminate the agreement. Further, in order to maintain our exclusive rights, we must achieve certain minimum annual sales of ANTARA until February 2012 or make payments to Ethypharm to compensate for the difference. Ethypharm also has a right of first refusal on any divestiture of our rights to ANTARA.



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We believe that we are currently in compliance with our obligations under the Etypharm 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. During 2007, we recorded approximately \$471,000 related to a minimum royalty obligation to Etypharm. Moreover, Etypharm's right of first refusal on a divestiture of our rights to ANTARA may adversely affect our ability to effect a change of control or sale of our assets.

*FACTIVE*

We have an exclusive license from LG Life Sciences to develop and market FACTIVE 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, Vatican City, Poland, Czech Republic, Slovakia, Slovenia, Hungary, Estonia, Latvia, Lithuania, Liechtenstein, Malta, Cyprus, Romania, Bulgaria, Croatia, Serbia and Montenegro, Bosnia and Herzegovina, Albania and the Former Yugoslav Republic of Macedonia. 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 with LG Life Sciences also requires that we achieve a minimum gross sales level of \$30 million from our licensed territories over a 12-month period of time starting on the third anniversary from the launch of FACTIVE in the U.S. in 2004 which, if not met, LG Life Sciences could elect to terminate the agreement and have the technology be 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 and meet all of our obligations due to the limitations on our resources and the many risks of conducting clinical trials, as described below in Clinical trials are costly, time consuming and unpredictable, and we have limited experience conducting and managing necessary preclinical and clinical trials for our product candidates and the challenges inherent in the commercialization of new products as described above in Our product candidates will face significant competition in the marketplace.

LG Life Sciences has the obligation under the agreement to diligently maintain its patents and the patents of third parties to which it has rights that, in each case relating 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.

In February 2006, we 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. In August 2006, we entered into a Supply, Development and Marketing Agreement with Abbott Laboratories, Ltd. (Abbott Canada), the Canadian affiliate of Abbott. Under this agreement, we are obligated to exclusively supply all finished packaged FACTIVE product required by Abbott Canada. In December 2006, we entered into a License, Supply and Marketing Agreement with Menarini International Operation Luxembourg SA (Menarini), whereby we sublicensed our rights to sell FACTIVE tablets in Europe to Menarini. Under the terms of our agreement with Menarini, Menarini is also obligated to exclusively purchase from us, and we must exclusively supply, all API for FACTIVE to be sold in Europe for the earlier to occur of the expiration of the life of certain patents covering the product or expiration of data exclusivity. We believe that, together with our manufacturing partners, we will be able to meet such

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supply and other obligations under these sublicense and supply agreements but can make no assurances that we will be able to remain in compliance with such responsibilities, which would result in our breach of such agreement.

**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 55 issued U.S. patents, approximately 57 pending U.S. patent applications, approximately 58 issued foreign patents and approximately 111 pending foreign patent applications. 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 Development, License and Supply Agreement with Ethypharm, S.A., we assumed all of the rights and obligations related to the development, manufacturing, marketing and sale of ANTARA in the United States. This license includes one issued U.S. patent and several pending patent applications. In conjunction with the financing of our acquisition of ANTARA, we entered into a Security Agreement with Paul Royalty Fund Holdings II, LP, an affiliate of Paul Capital Partners, or Paul Capital, under which our wholly-owned subsidiary granted Paul Capital a security interest in all of its assets, including all rights to ANTARA intellectual property, in order to secure its performance under the financing agreements with Paul Capital. These patents and applications include claims that relate to pharmaceutical compositions containing fenofibrate using the drug delivery technologies incorporated in ANTARA, methods of their use and treatment, and methods of preparing the same. The patent issued to Ethypharm which is listed in the FDA Orange Book is set to expire in 2020.

Under our license agreement with LG Life Sciences, we obtained an exclusive license to develop and market gemifloxacin in certain territories. This license covers 16 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. We have received a Notice of Final Determination from the U.S. Patent and Trademark Office on our patent term extension application for U.S. Patent No. 5,776,944 extending its patent term 659 days to April 4, 2017. The principal U.S. patents for FACTIVE are currently set to expire at various dates, ranging from 2015 to 2019.

On January 8, 2008 the United States Patent and Trademark Office (USPTO) issued us U.S. Patent No. 7,317,001 relating to the treatment of *C. difficile* associated disease (CDAD) using Ramoplanin. We received a patent term adjustment of 565 days thus extending the term through December 20, 2024. In addition to the recently issued patent, we have an additional patent which includes claims relating to methods of manufacturing Ramoplanin. We also have several applications pending relating to additional novel uses of Ramoplanin as well as formulations containing 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 we believe we would receive under the Hatch-Waxman Act in the U.S. and the ten years of market exclusivity in Europe available through the European Medicines Agency (EMA), because Ramoplanin would be a new chemical entity not previously marketed commercially.

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. We acquired exclusive rights to ANTARA trademarks, trade names, domain names and logos. After becoming aware that Antara Biosciences, Inc. filed trademark applications with the USPTO for the ANTARA and ANTARA BIOSCIENCES marks in connection with biotechnology related goods and services we filed a complaint in Federal District Court

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alleging, among other things, trademark infringement seeking to enjoin ANTARA BIOSCIENCES from using the ANTARA mark. We have reached a settlement with ANTARA BIOSCIENCES whereby they have agreed to abandon their ANTARA trademark applications and cease using the ANTARA marks. Accordingly we have dismissed our complaint before the Federal District Court.

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;

the April 30, 2007 U.S. Supreme Court decision in *KSR International Co. vs. Teleflex, Inc.* may raise the standard for patentability for both patent applications and holders, thus making it more difficult to either obtain patents or withstand challenges to patentability based on a determination of obviousness;

other companies may independently develop similar or alternative technologies or duplicate our technologies; and

the patents may be narrow in scope and accordingly other companies may design around technologies we have licensed or developed.

### **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 an 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.



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### **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 highest between December 1 and March 31 as the incidence of respiratory tract infections, including CAP and AECB, tends to increase during the winter months. In addition, fluctuations in the duration and 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 one quarter may not be indicative of the results for any other quarter or for the entire year.

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

To obtain FDA approval to market a new drug product or to expand the approved uses of an existing product, we or our partners must demonstrate proof of safety and efficacy in humans. To meet these requirements, we or our partners will have to conduct extensive testing, including potentially preclinical testing and adequate and well-controlled clinical trials. Conducting clinical trials is a lengthy, time-consuming and expensive process. The length of time required to conduct required studies may vary substantially according to the type, complexity, novelty and intended use of the product candidate, and often can be several years or more per trial. Delays associated with products for which clinical trials are required may cause us to incur additional operating expenses.

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 but did not meet its primary endpoint. Prior clinical and preclinical trials for Ramoplanin were conducted by Vicuron and its licensees, from whom we acquired rights to Ramoplanin. Although we have agreed with the FDA to a Special Protocol Assessment regarding specific components of a Phase III program that, if completed successfully, would support regulatory approval for the indication, we can give no assurance that as clinical trials proceed or as part of an NDA review process, if any, the FDA will not determine that a previously approved Special Protocol Assessment for a particular protocol is no longer valid. Additionally, in October 2007, the FDA issued draft guidance on the use of non-inferiority studies to support approval of antibiotics. Under this draft guidance, the FDA recommends that for some antibiotic indications, sponsor companies carefully consider study designs other than non-inferiority, such as placebo-controlled trials demonstrating the superiority of a drug candidate to placebo. While the indications identified by the FDA in the draft guidance are not indications which we are currently pursuing, the draft guidance does not articulate clear standards or policies for demonstrating the safety and efficacy of antibiotics generally. The lack of clear guidance from the FDA creates uncertainties about the standards for the approval of antibiotics could delay or ultimately prevent commercialization of new antibiotic product candidates such as Ramoplanin or additional indications for FACTIVE. If the trials or the filings are delayed or not approved by the FDA, our business may be adversely affected.

If we choose to pursue additional indications or expand the label for ANTARA or FACTIVE, or are required to conduct additional clinical trials, we may not be able to demonstrate the safety and efficacy of FACTIVE or ANTARA for those indications 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 or label expansion.

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.

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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 pharmaceutical 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 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.

### **We could experience delays in clinical development which could delay anticipated product launches.**

The speed with which we are able to complete clinical trials for future product candidates, when and if we, or any third party with whom we partner, elects to commence Phase III development of Ramoplanin, 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 disease incidence 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 including the FDA's recent draft guidance released in October 2007 relating to Antibacterial Drug Products: Use of Noninferiority Studies to Support Approval; 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.

### **We depend on key personnel, including members of our direct sales force, in a highly competitive market for such skilled personnel.**

We are highly dependent on the principal members of our senior management and key scientific, sales 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 executive officers: Steven M. Rauscher, President and Chief Executive Officer; Dominick Colangelo, Esq., Executive Vice President, Corporate Development and Operations; and Philippe M. Maitre, Senior Vice President and Chief Financial Officer. The term of each employment agreement continues until it is terminated by the officer or Oscient.

Our future success is dependent upon our ability to attract and retain additional qualified sales and marketing, clinical development, scientific and managerial personnel. Like others in our industry, we may face, and in the past we have faced from time to time, difficulties in attracting and retaining certain employees with the requisite expertise and qualifications. We believe that our historical recruiting periods and employee

turnover rates are similar to those of others in our industry; however, we cannot be certain that we will not encounter greater difficulties in the future.

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With routine employee turnover, we also face the risk of being unable to enforce our rights under non-compete and non-solicitation provisions as well as confidentiality obligations that protect the Company. We also need to guard against the same obligations that our employees or our potential employees have with their former employers.

**Changes in the expensing of stock-based compensation have resulted and will continue to 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 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 the expense for the fair value of stock options granted to employees and the fair value of 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 effect on earnings, it may be difficult for us to attract and retain qualified scientific, technical and business personnel.

**Failure to obtain or maintain regulatory approvals in foreign jurisdictions will prevent us from marketing FACTIVE abroad.**

We have entered into commercialization relationships with Pfizer Mexico, Abbott Canada and Menarini whereby we sublicensed our rights to sell FACTIVE tablets in Mexico to Pfizer Mexico, in Canada to Abbott Canada and in Europe to Menarini. Obtaining foreign approvals may require additional trials and expense. Further, in order to market FACTIVE in Europe, we or our distribution partners may need to obtain multiple regulatory approvals. For instance, our predecessor's original regulatory filing in the United Kingdom 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. Further, based on the amendment of our agreement with Abbott Canada of January 31, 2008, Abbott Canada is no longer obligated to pursue the CAP and ABS indications in Canada. If our partners are unsuccessful in their efforts to obtain and/or expand their respective marketing approvals, the revenues that we expect to obtain from the sales of FACTIVE could be significantly limited.

**We rely on operational data obtained from third party vendors which could be inaccurate.**

We rely on prescription and wholesaler data obtained from industry-accepted, third-party data sources. These third-party data projections may not accurately reflect actual prescriptions or trade levels of inventory. If this data turns out to be inaccurate or unreliable and our controls are not effective, there could be an adverse effect on our ability to properly manage inventory and our financial performance.

## **RISKS RELATED TO OUR INDUSTRY**

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

Our ability to commercialize ANTARA capsules, FACTIVE tablets, Ramoplanin and our future products will depend, in part, on the extent to which reimbursement for such products will be available from third-party payers, such as Medicare, Medicaid, health maintenance organizations, health insurers and other public and private payers. We cannot assure you that third-party payers will pay for such products or will establish and maintain price levels sufficient for realization of an appropriate return on our investment in product development. If adequate coverage and reimbursement levels are not provided by government and private payers for use of our products, our products may fail to achieve market acceptance and our results of operations may be materially adversely affected. Under the Medicare Part D outpatient prescription drug benefit, Medicare beneficiaries (primarily the elderly over 65 and the disabled) may enroll in private drug plans. There are multiple types of Part



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D plans and numerous plan sponsors, each with its own formulary and product access requirements. The plans have considerable discretion in establishing formularies and tiered co-pay structures and in placing prior authorization and other restrictions on the utilization of specific products. In addition, Part D plan sponsors are permitted and encouraged to negotiate rebates with manufacturers. The profitability of our products may depend on the extent to which they enjoy preferred status on the formularies of a significant portion of the largest Part D prescription drug plans. Our ability to obtain such preferred status on favorable economic terms cannot be assured. Additionally, the Part D program has been the subject of much controversy since its inception in 2003, and significant amendments, including an amendment to authorize the Federal Government to directly negotiate drug prices with manufacturers, are possible. Such amendments could adversely affect our anticipated revenues and results of operations, possibly materially.

Most state Medicaid programs have established preferred drug lists, or PDLs, and the process, criteria and timeframe for obtaining placement on the PDL varies from state to state. Under the Medicaid drug rebate program, a manufacturer must pay a rebate for Medicaid utilization of a product. The rebate is based on the greater of (i) a specified percentage of the product's average manufacturer price (AMP) or (ii) the difference between the product's AMP and the best price offered by the manufacturer. In addition, many states have established supplemental rebate programs as a condition for including a drug product on a PDL. The profitability of our products may depend on the extent to which they appear on the PDLs of a significant number of state Medicaid programs and the amount of the rebates that must be paid to such states. In addition, there is significant fiscal pressure on the Medicaid program, and amendments to lower the pharmaceutical costs of the program are possible. Such amendments 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 ANTARA capsules, FACTIVE tablets, Ramoplanin or any of our future products will be added to payers' formularies, whether our products will have preferred status to alternative therapies, nor whether the formulary decisions will be conducted in a timely manner. We may also decide to enter into discount or formulary fee arrangements with payers, which could result in our receiving lower or discounted prices for 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 ANTARA and FACTIVE and our anticipated revenues and results of operations could be adversely affected.

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

The use of any of our product candidates in clinical trials, and the sale of any approved products, might expose us to product liability claims. We currently maintain, and we expect that we will continue to maintain, product liability insurance coverage in the amount of \$10.0 million per occurrence and \$10.0 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

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a claim brought successfully against us. Furthermore, whether or not we are ultimately successful in defending any such claims, we might be required to direct financial and managerial resources to such defense and adverse publicity could result, all of which could harm our business.

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

## **RISKS RELATED TO THE SECURITIES MARKET**

### **Our stock price is highly volatile.**

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

our ability to successfully commercialize ANTARA capsules and FACTIVE tablets;

the revenues that we may derive from the sale of ANTARA capsules and FACTIVE tablets, as compared to analyst estimates or to our own guidance;

our ability to enter into transactions to acquire, license or co-promote additional products;

the results of any clinical trials that we may conduct and the pace of our progress in those clinical trials;

the results of clinical trials conducted by partners for Ramoplanin or products developed from any of our legacy alliances and the pace of progress in those clinical trials;

whether we will be able to successfully integrate any additional products that we acquire, license or co-promote into our sales and marketing efforts;

the timing of the achievement of 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 pharmaceutical industry generally;

our ability to meet the continued listing requirements for The NASDAQ Global Market;

price and volume fluctuations in the stock market at large which do not relate to our operating performance;

variations in our rates of product returns, allowances and rebates and discounts;

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

comments by securities analysts, or our failure to meet market expectations, including our projected financial performance.

Over the two-year period ending December 31, 2007 the closing price of our common stock as reported on The NASDAQ Global Market ranged from a high of \$22.24 to a low of \$1.23. 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.

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**Our common stock is subject to delisting from The NASDAQ Global Market and there can be no assurance that we will complete our plan for compliance or that The NASDAQ will consider our compliance satisfactory, and that we will retain our listing.**

On August 17, 2007, we were notified by NASDAQ that our common stock was subject to delisting from The NASDAQ Global Market based upon our failure to satisfy the \$50 million market value of listed securities requirement for the previous ten consecutive trading days (pursuant to Rule 4450(b)(1)(A) of the NASDAQ Marketplace Rules). We were granted a thirty calendar-day period to regain compliance with the requirement. We did not regain compliance, and on September 18, 2007, we were notified by NASDAQ that trading in our securities would be suspended on September 27, 2007, unless we appealed the NASDAQ staff's determination. We requested a hearing before the NASDAQ Listing Qualifications Panel (NASDAQ Panel) and on November 8, 2007, presented our plan to evidence compliance with the alternative listing standard which requires \$50 million in total assets and \$50 million in total revenue in either the most recent fiscal year, or two of the three most recent fiscal years, according to Marketplace Rule 4450(b)(1)(B), upon the filing of the Form 10-K for the fiscal year ended December 31, 2007.

On November 30, 2007, the NASDAQ Panel granted our request for continued listing of our securities on The NASDAQ Global Market. Our continued listing is subject to the filing of our Form 10-K for the fiscal year ending December 31, 2007 on or before February 6, 2008, which evidences over \$50 million in revenue and over \$50 million in total assets as well as continued compliance with other listing requirements for The NASDAQ Global Market. Even if NASDAQ reinstates us following the filing of this Annual Report on Form 10-K, there can be no assurance that we will be able to meet these requirements for continued listing in the future.

In order to fully comply with the terms of the exception granted by the NASDAQ Panel, we must be able to demonstrate compliance with all requirements for continued listing on The NASDAQ Global Market. If we are unable to do so, our common stock may be delisted from The NASDAQ Global Market. In the event that we are delisted from The NASDAQ Global Market, we may not be able to meet the requirements necessary for the transfer to or listing on another national exchange, including The NASDAQ Capital Market.

**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 ANTARA capsules and FACTIVE tablets, and in the case of FACTIVE, seasonal fluctuations in the duration and severity of the annual respiratory tract infection season;

the level of acceptance by physicians and third party payers of ANTARA and FACTIVE;

the progress of any future clinical trials for our products;

the progress of any clinical trials conducted by partners for Ramoplanin or products developed through our legacy alliances;

our success in concluding transactions to acquire additional approved products and product candidates, and the pace of our commercialization of such additional products;

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.

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We will not be able to control many of these factors. In addition, if our revenues in a particular period do not meet expectations, we may not be able to adjust our expenditures in that period, which could cause our business

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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 1 B. 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. During 2007, we incurred aggregate rental costs, excluding maintenance and utilities, for our Corporate headquarter Waltham facility of approximately \$833,000. Additionally, in 2006 we incurred approximately \$1.8 million which included obligations under a lease for approximately 81,000 square feet of space at our former executive offices located at 100 Beaver Street, Waltham, Massachusetts, which expired on November 15, 2006. We subleased approximately 47,000 square feet at our former Beaver Street facility, and we received approximately \$1.6 million in sublease income in 2006.

In 2007, we expanded our commercial sales and marketing capabilities by adding offices in New Jersey. Our commercial sales and marketing offices are located at 23 Orchard Road, Suite B103, Skillman, New Jersey. We lease approximately 10,000 square feet of space at the Orchard Road facility and our lease term, which extends five years, will begin in early 2008 and expire in 2013.

We also maintain a west coast lease 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 \$4.7 million. The lease for this facility expires on February 28, 2011 and we have subleased to third parties approximately 61,300 square feet of the facility through various dates ranging from October 31, 2008 to February 28, 2011. In 2007, we received approximately \$2.6 million in sublease income from the west coast subleases.

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

On August 23, 2007, Thomas Weisel Partners LLC ( Thomas Weisel ) filed a Demand for Arbitration against the Company with the American Arbitration Association ( AAA ). In the Demand for Arbitration, Thomas Weisel alleged that the Company breached the parties Engagement Letter dated December 7, 2006 (the Engagement Letter ), by alleging the Company failed to include Thomas Weisel as its financial advisor in its convertible debt transaction in April 2007. The Company and Thomas Weisel mutually agreed to settle the dispute and all alleged claims and causes of action against the Company were dismissed on January 3, 2008.

### **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 Global Market under the symbol OSCI. The table below sets forth the range of high and low sale prices for each fiscal quarter during 2007 and 2006 as reported by the NASDAQ Global Market, adjusted to account for the effect of the 1-for-8 reverse stock split effective on November 15, 2006.

	2007		2006	
	High	Low	High	Low
First Quarter	\$ 5.50	\$ 4.10	\$ 22.48	\$ 14.16
Second Quarter	7.78	4.45	16.32	6.16
Third Quarter	4.75	2.48	11.60	4.40
Fourth Quarter	3.27	1.16	9.44	4.15

As of February 1, 2008, there were approximately 1,264 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.

**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	1,089,648	\$ 23.88	480,503
Equity compensation plans not approved by security holders (1)	173,188	2.76	239,537
Total	1,262,836	\$ 20.75	720,040

- (1) As described on the Company's Form S-8 filed on October 1, 2007, the Board of Directors approved the Company's 2007 Employment Inducement Award Plan (the 2007 Inducement Plan) on August 13, 2007, and authorized 500,000 shares of common stock for issuance under the 2007 Inducement Plan. The 2007 Inducement Plan provides for the grant of non-qualified stock options and restricted stock to new employees.

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**Company Purchases of Equity Securities**

We did not make any purchases of our common stock during the year ended December 31, 2007.

\* \$100 invested on 12/31/02 in stock or index-including reinvestment of dividends.  
Fiscal year ending December 31.

*Notwithstanding anything to the contrary set forth in any of the Company's previous or future filings made under the Securities Act or the Exchange Act that might incorporate by reference this annual report or future filings made by the Company under those statutes, the preceding Stock Performance Graph and the information relating to it is not soliciting material and is not deemed filed with the Securities and Exchange Commission, and shall not be deemed incorporated by reference into any of those such prior filings or into any future filings made by the Company under those statutes.*

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[www.researchdatagroup.com/S&P.htm](http://www.researchdatagroup.com/S&P.htm)



**Table of Contents****Item 6. Selected Financial Data**

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

We derived the statement of operations data for the years ended December 31, 2007, 2006 and 2005 and the balance sheet data as of December 31, 2007 and 2006 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, 2004 and 2003 and the balance sheet data as of December 31, 2005, 2004 and 2003 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).

	<b>For the Year Ended December 31,</b>				
	<b>2007</b>	<b>2006(3)</b>	<b>2005</b>	<b>2004(4)</b>	<b>2003</b>
<b>Revenues (net):</b>					
Product sales	\$ 78,458	\$ 38,244	\$ 20,458	\$ 4,067	\$
Co-promotion		6,890	2,954		
Other	1,511	1,018	197	2,546	7,009
<b>Total net revenues (1)</b>	<b>79,969</b>	<b>46,152</b>	<b>23,609</b>	<b>6,613</b>	<b>7,009</b>
Costs of product sales and operating expenses	117,965	118,071	112,281	97,229	39,943
<b>Loss from operations</b>	<b>(37,996)</b>	<b>(71,919)</b>	<b>(88,672)</b>	<b>(90,616)</b>	<b>(32,934)</b>
Net other income (expense)	8,527	(6,379)	79	(2,863)	3,546
<b>Loss from continuing operations before income tax</b>	<b>(29,469)</b>	<b>(78,298)</b>	<b>(88,593)</b>	<b>(93,479)</b>	<b>(29,388)</b>
Provision for income tax	(384)	(179)			
<b>Net loss from continuing operations</b>	<b>(29,853)</b>	<b>(78,477)</b>	<b>(88,593)</b>	<b>(93,479)</b>	<b>(29,388)</b>
Income (loss) from discontinued operations				208	(401)
<b>Net loss</b>	<b>\$ (29,853)</b>	<b>\$ (78,477)</b>	<b>\$ (88,593)</b>	<b>\$ (93,271)</b>	<b>\$ (29,789)</b>
<b>Net loss per common share basic and diluted (2)</b>	<b>\$ (2.19)</b>	<b>\$ (6.58)</b>	<b>\$ (9.26)</b>	<b>\$ (10.61)</b>	<b>\$ (9.06)</b>
<b>Weighted average basic and diluted common shares outstanding (2)</b>	<b>13,601</b>	<b>11,925</b>	<b>9,569</b>	<b>8,794</b>	<b>3,286</b>

- (1) Does not include income (loss) from discontinued operations related to our genomics business.
- (2) Adjusted to account for the effect of the one-for-eight reverse stock split effective on November 15, 2006.
- (3) We acquired the ANTARA assets on August 18, 2006.
- (4) We completed a merger with GeneSoft Pharmaceuticals on February 6, 2004.

	<b>As of December 31,</b>				
	<b>2007</b>	<b>2006</b>	<b>2005</b>	<b>2004</b>	<b>2003</b>
Cash and cash equivalents, restricted cash, and long and short-term marketable securities	\$ 52,466	\$ 44,808	\$ 80,044	\$ 176,628	\$ 28,665
Working capital	42,011	40,444	77,750	156,021	18,897
Total assets	274,184	279,407	241,095	340,560	40,516
Long-term liabilities	268,906	250,977	191,289	193,397	292

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Shareholders (deficit) equity	(28,715)	(1,996)	28,101	114,400	29,940
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**Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations**

**Overview**

Oscient Pharmaceuticals Corporation ( we , us , or the Company ) is a commercial-stage pharmaceutical company marketing Food and Drug Administration (FDA)-approved products in the United States. Our strategy is to grow the sales of our existing products and to gain access to new products via transactions, including acquisition, in-licensing and co-promotion. We have developed a commercial infrastructure, including a national sales force calling on targeted primary care physicians, cardiologists, endocrinologists and pulmonologists in the United States.

We currently market two products: ANTARA® (fenofibrate) capsules, a cardiovascular product, and FACTIVE® (gemifloxacin mesylate) tablets, a fluoroquinolone antibiotic. ANTARA is approved by the FDA to treat hypercholesterolemia (high blood cholesterol) and hypertriglyceridemia (high triglycerides) in combination with a healthy diet. We license the rights to ANTARA from Ethypharm S.A of France (Ethypharm) and began promoting ANTARA in late August 2006. In 2007, ANTARA generated approximately \$59 million in net revenues. FACTIVE is indicated for the treatment of community-acquired pneumonia of mild to moderate severity, or CAP, and acute bacterial exacerbations of chronic bronchitis, or AECB. We license the rights to gemifloxacin, the active ingredient in FACTIVE tablets, from LG Life Sciences of the Republic of Korea (LG Life Sciences) and launched FACTIVE in the U.S. market in September 2004. In 2007, FACTIVE generated approximately \$20 million in net revenues.

Additionally, we have a novel, late-stage antibiotic candidate, Ramoplanin, for the treatment of *Clostridium difficile*-associated disease, or CDAD. We have made the strategic decision to concentrate our financial resources on building our revenues for products promoted to community-based physicians in the United States and are currently seeking to out-license, co-develop or sell the rights to Ramoplanin to a partner.

We have incurred significant operating losses in the past. As of December 31, 2007, we had an accumulated deficit of approximately \$446 million. We expect to incur additional operating losses due to the implementation of manufacturing, distribution, marketing and sales capabilities.

On August 17, 2007, we were notified by NASDAQ that our common stock was subject to delisting from The NASDAQ Global Market based upon our failure to satisfy the \$50 million market value of listed securities requirement for the previous ten consecutive trading days pursuant to Rule 4450(b)(1)(A) of the Nasdaq Marketplace Rules. We did not meet the alternative listing standard which requires \$50 million in total assets and \$50 million in total revenue in either the last fiscal year, 2006, or two of the three most recent fiscal years, according to Marketplace Rule 4450(b)(1)(B). We were granted a thirty (30) calendar-day period to regain compliance with the requirement. We did not regain compliance, and on September 18, 2007, we were notified by NASDAQ that our common stock was subject to delisting as a result of the deficiency.

We requested a hearing before the NASDAQ Listing Qualifications Panel and, on November 8, 2007, we presented our plan to evidence compliance with the alternative listing standard which requires \$50 million in total assets and \$50 million in total revenue in either the most recent fiscal year, or two of the three most recent fiscal years, according to Marketplace Rule 4450(b)(1)(B), upon the filing of the Form 10-K for the fiscal year ended December 31, 2007. On November 30, 2007, the NASDAQ Panel granted our request for continued listing of our securities on The NASDAQ Global Market. Our continued listing is subject to the filing of the our Form 10-K for the fiscal year ending December 31, 2007 on or before February 6, 2008, which evidences over \$50 million in revenue and over \$50 million in total assets. For the fiscal year ending December 31, 2007, we had revenue of approximately \$80 million and total assets of approximately \$274 million.

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**ANTARA**

ANTARA is a once-daily formulation of fenofibrate approved for use in combination with a diet restricted in saturated fat and cholesterol to reduce elevated LDL-C ( bad cholesterol), triglyceride and apolipoprotein B (free floating fats in the blood) levels and to increase HDL-C ( good cholesterol) in adult patients with high cholesterol or an abnormal concentration of lipids in the blood. Fenofibrate products work primarily to lower triglycerides and increase HDL-C, which makes the drug an attractive alternative for those patients whose LDL-C is well controlled. ANTARA received FDA approval in November 2004. We began marketing ANTARA in 43 mg and 130 mg doses in August 2006.

On August 18, 2006, we acquired rights to ANTARA in the United States from Reliant Pharmaceuticals Inc. (Reliant) for \$78 million plus approximately \$4.3 million for ANTARA inventory, excluding estimated transaction costs. Under the terms of our acquisition of ANTARA, we assumed certain of Reliant's liabilities related to ANTARA, including obligations to make certain royalty and milestone payments on sales of ANTARA, and we were assigned rights to an exclusive license from Ethypharm S.A. (Ethypharm). In order to maintain the exclusivity of our rights, we must achieve minimum annual sales in the United States until February 2012 or alternatively compensate Ethypharm for any shortfall. During 2007, we recorded approximately \$471,000 related to the minimum royalty obligation to Ethypharm. In addition, a sales-based milestone was met which resulted in the Company paying \$400,000 to Ethypharm in the fourth quarter of 2006. We recorded this milestone payment as a liability in accordance with purchase accounting. During the term of the agreement with Ethypharm, we are obligated to pay a royalty on net sales of ANTARA in the U.S., including a royalty on other fenofibrate monotherapy products in formulations and dosage forms that may be substantially similar or identical to ANTARA developed by us. The license term expires in February 2020 and, absent notice of termination by either party, automatically renews for consecutive periods of two (2) years each. Under the terms of the agreement, at our option, Ethypharm is obligated to either manufacture and deliver to us finished fenofibrate product or deliver API to us for encapsulation and packaging. Ethypharm also has a right of first refusal on any divestiture of the ANTARA rights by us. Additional Oscient obligations under the Ethypharm agreement include using commercially reasonable efforts to maintain a sales force of at least 150 representatives through February 2008 and funding a portion of the active pharmaceutical ingredient safety stock that Ethypharm is required to maintain.

Pursuant to the terms of our acquisition of ANTARA from Reliant, we also acquired the New Drug Application, or NDA and the Investigational New Drug application, or IND, covering the ANTARA products in the United States, clinical data, inventory, the ANTARA® trademark in the United States and certain related contracts and licenses covering intellectual property rights related to the ANTARA products. We also assumed certain of Reliant's liabilities related to the ANTARA products.

We are not required to pay Reliant a royalty on the sale of the ANTARA products; however, we are required to pay a low single-digit royalty to Reliant for a specified time period on net sales of any line extensions and improvements to the ANTARA products that we develop, which include any product containing fenofibrate as its API. We currently do not pay royalties to Reliant. We also agreed that we would not, at any time prior to August 2016, develop or sell any product in the United States that is a combination of fenofibrate and an omega-3 compound without the prior written consent of Reliant. On December 19, 2007, Reliant was acquired by GlaxoSmithKline.

ANTARA capsules are covered by a U.S. patent relating to formulations containing fenofibrate and methods of preparing the same that extend through August 2020. In addition, Ethypharm has filed additional patent applications which relate to the formulation and we were assigned a patent application which was filed by Reliant relating to methods of treatment. If issued, we believe these patents may provide ANTARA additional patent protection.

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**FACTIVE**

*Overview*

FACTIVE was approved by the FDA in 2003 for the treatment of community-acquired pneumonia of mild to moderate severity, or CAP, and acute bacterial exacerbations of chronic bronchitis, or AECB.

We license from LG Life Sciences the right to develop and commercialize FACTIVE (gemifloxacin) tablets, a 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, Vatican City, Poland, Czech Republic, Slovakia, Slovenia, Hungary, Estonia, Latvia, Lithuania, Liechtenstein, Malta, Cyprus, Romania, Bulgaria, Croatia, Serbia and Montenegro, Bosnia and Herzegovina, Albania and the Former Yugoslav Republic of Macedonia. 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 issued patents for composition of matter expires in 2018. The patent term could extend further in countries outside of the U.S. 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 API. LG Life Sciences currently supplies the FACTIVE API from its manufacturing facility in South Korea.

The agreement with LG Life Sciences also requires that we achieve a minimum gross sales level of \$30 million from our licensed territories over a 12-month period of time starting on the third anniversary from the launch of FACTIVE in the U.S. in 2004 which, if not met, LG Life Sciences could elect to terminate the agreement and have the technology be 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 conducting clinical trials, filing drug approval applications with the FDA and other applicable regulatory authorities and marketing, distributing and selling of gemifloxacin in our territory.

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 (i) the expiration of the patents covering FACTIVE in such country or (ii) the expiration of data exclusivity in Mexico, Canada or the European Union respectively, or 2014 in the U.S. We are also obligated to make aggregate milestone payments of up to \$40 million to LG Life Sciences (including milestone payments required by the amendments described below) upon achievement of additional regulatory approvals and sales thresholds.

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, up-front 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. 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 (which payments were made to LG Life Science in February 2006 and August 2006, respectively) as well as upon receipt of regulatory approval of FACTIVE in each of such countries. Additionally, on December 27, 2006, we amended our agreement with LG Life Sciences to reduce future royalties payable to LG Life Sciences for sales of FACTIVE tablets in Europe and to provide for a reduction in

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the supply price for the API for FACTIVE for product to be sold in Europe. In lieu of milestone payments previously agreed to by the parties, this amendment also requires us to pay LG Life Sciences a portion of any milestone or license fee payments we receive from our European partner.

*Commercialization and Development*

With respect to additional development initiatives, we completed a clinical trial designed to demonstrate that a five-day course of FACTIVE for the treatment of mild to moderate CAP is as effective as the previously approved seven-day course of treatment. On September 21, 2006, we received an approvable letter from the FDA for the supplemental New Drug Application (sNDA) seeking approval for the five-day treatment of CAP with FACTIVE tablets. In accordance with the letter, we provided clarification and additional interpretation regarding certain data included in the application to assist the FDA in its evaluation. On May 1, 2007, the FDA approved FACTIVE for the five-day treatment of CAP.

As part of the FACTIVE development program, several studies relating to acute bacterial sinusitis, or ABS, were completed, and, in November 2005, we filed an sNDA for ABS. In September 2006, the FDA's Anti-Infective Drugs Advisory Committee voted not to recommend approval of this sNDA. In November 2006, we voluntarily withdrew our sNDA seeking approval of the ABS indication.

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. In exchange for those rights, Pfizer Mexico has paid us an up-front payment and has agreed to pay us milestone payments upon obtaining certain regulatory approvals and sales goals as well as royalties on future sales. The up-front payment is being recognized as revenue over the term of our continuing obligations under the agreement. 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 API 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 nine months prior written notice. Upon termination, Pfizer Mexico is obligated to assign any and all rights to regulatory approvals in Mexico to us or our designee. Pfizer Mexico is currently marketing FACTIVE-5 in Mexico for the treatment of CAP, AECB and ABS.

On August 9, 2006, we granted the commercialization rights to FACTIVE tablets in Canada to Abbott Laboratories, Ltd. (Abbott Canada), the Canadian affiliate of Abbott. In exchange for those rights, Abbott Canada agreed to a transfer price on product purchases and to make certain payments to us upon achievement of certain regulatory and sales milestones. FACTIVE is currently approved in Canada for the five-day treatment of AECB. We subsequently amended the agreement on January 31, 2008 whereby Abbott Canada's development and commercialization obligations were substantially reduced. In accordance with the terms of the amendment, Abbott Canada will continue to maintain FACTIVE tablets in its current product price list and it will continue to pay us a transfer price on FACTIVE tablets purchases. Abbott Canada is not required to pursue the CAP and ABS indications. Additionally, the amendment provides that we can terminate the agreement at any time with prior notice to Abbott Canada and Abbott Canada can terminate with prior notice to us after November 30, 2008.

We entered into a License, Supply and Marketing Agreement with Menarini International Operation Luxembourg SA (Menarini), a wholly-owned subsidiary of Menarini Industrie Farmaceutiche Riunite S.r.l. dated December 28, 2006, whereby we sublicensed our rights to sell FACTIVE tablets in the European Union to Menarini. Under the terms of our agreement with Menarini, Menarini is responsible for obtaining regulatory approval for FACTIVE in the European Union. Oscient has agreed to reimburse Menarini for expenses associated with such regulatory development up to an agreed limit. Menarini has paid us an up-front payment and agreed to pay us milestone payments upon obtaining certain regulatory and reimbursement approvals and upon achieving certain annual net sales goals, which could total up to \$23 million if all the milestones are achieved.

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Menarini will pay us a transfer price on purchases of the active pharmaceutical ingredient, or API, for FACTIVE, which is determined based on a percentage of quarterly sales of FACTIVE by Menarini in Europe. Menarini is also obligated to exclusively purchase from us, and we must exclusively supply, all API for FACTIVE to be sold in Europe for the earlier of (i) the expiration of the life of certain patents covering the product or (ii) expiration of data exclusivity. Our agreement with Menarini may be terminated by either party upon the occurrence of certain termination events, including Menarini's right to terminate if the European regulatory authorities do not recommend approval of FACTIVE at various stages of the approval process with a package insert, or label, that meets certain requirements as to the safety, dosing and indications for which FACTIVE may be prescribed. Menarini may also terminate the agreement if it does not receive approval for reimbursement from European Union member countries that is above a certain minimum price per tablet. Upon termination, Menarini is obligated to assign any and all rights to regulatory approvals in the European Union to Oscient or its designee.

### **Research and Development Programs**

#### **FACTIVE**

As a condition to the approval to sell FACTIVE tablets, the FDA required, as a post-marketing study commitment, that we conduct a prospective, randomized study examining the activity of FACTIVE tablets (5,000 patients) versus 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 included patients of different ethnicities to gain safety information in populations not substantially represented in the existing clinical trial program. This Phase IV trial was initiated in the fall of 2004 and was completed in January 2007. The final report of the utilization study is scheduled for submission to the FDA in the first half of 2008. In the future, we need only to provide the FDA with annual reports containing safety information.

Additionally, in April 2005, we completed a Phase III trial examining the potential use of FACTIVE tablets for the five-day treatment of mild to moderate CAP. Based on the results of this study, in November 2005 we submitted an sNDA to the FDA for approval to promote the five-day treatment of FACTIVE tablets for this indication. On September 21, 2006, we received an approvable letter from the FDA for the sNDA seeking approval for the five-day treatment of CAP with FACTIVE tablets. In accordance with the letter, we provided clarification and additional interpretation regarding certain data included in the application to assist the FDA in its evaluation. On May 1, 2007, the FDA approved FACTIVE for the five-day treatment of CAP.

#### **Ramoplanin**

We have a novel, late-stage investigational antibiotic candidate, Ramoplanin, under investigation 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 rights to the manufacturing, development and commercialization of Ramoplanin.

We agreed with the FDA to a Special Protocol Assessment (SPA) regarding the specific components of a Phase III program that, if completed successfully, would support regulatory approval for the indication. With the acquisition of ANTARA, we have made the strategic decision to concentrate our financial resources on building its revenues for products promoted to community-based physicians in the United States and are currently seeking to out-license, co-develop or sell our rights to Ramoplanin to a partner.

### **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

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Statements of this Annual Report on Form 10-K. Our preparation of our financial statements requires us to make estimates and assumptions that affect the reported amount of assets and liabilities, the 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 ANTARA capsules and FACTIVE tablets. In the second quarter of 2005, we began recognizing co-promotion revenue in connection with our co-promotion agreement with Auxilium Pharmaceuticals, Inc. (Auxilium), which terminated on August 31, 2006. Other historical sources of revenue include biopharmaceutical alliances and royalties from our divested genomic services business. In future periods, product revenues will continue to increase based on anticipated increased volume of prescriptions of ANTARA capsules and FACTIVE tablets. Conversely, we expect our revenues derived from biopharmaceutical alliances will continue to decrease.

Although ANTARA revenue results are anticipated to be steady throughout our fiscal year, we expect demand for FACTIVE to be highest from December to March as the incidence of respiratory tract infections, including CAP and AECB, tends to increase during the winter months. 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 for FACTIVE, 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 (SAB) No. 104, Revenue Recognition (a replacement of SAB 101) (SAB No. 104) 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 that risk of loss has passed. The cost of ANTARA and FACTIVE associated with amounts recorded as deferred revenue is recorded in inventory until such time as risk of loss has passed.

### **Other Revenues**

Other revenues primarily consist of sublicensing revenues related to FACTIVE. We recognize revenue in accordance with SAB No. 104 and Emerging Issues Task Force (EITF) Issue No. 00-21, Revenue Arrangements with Multiple Deliverables (EITF No. 00-21). In accordance with EITF No. 00-21, the up-front license payments related to the various sublicense agreements will be recognized as revenue over the term of our continuing obligations under the arrangements which range from eighteen months to thirty-three months. Substantive milestones achieved are recognized as revenue when earned and when payment is reasonably assured, if we have completed our remaining obligations under the arrangement. If we have further obligations, milestone payments are recognized as revenue if we have sufficient evidence of fair value for its remaining obligations otherwise the milestone payment is recognized as revenue over the remaining performance period.

We expense incremental direct costs associated with sublicense agreements in the period in which the expense is incurred.



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

In the U.S., we sell ANTARA and FACTIVE 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 four categories of discounts and allowances that suggest that all or part of the revenue should not be recognized at the time of the delivery product returns, cash discounts, rebates, and special promotional programs.

#### *Product Returns*

Factors that are considered in our estimate of future ANTARA and FACTIVE 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, actual and historical return rates for expired lots, return rates for similar competitive antibiotic and cardiovascular 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 twelve months subsequent to, the expiration date of our product. ANTARA capsules and FACTIVE tablets each have a 36-month expiration period from the date of manufacturing. During 2007, we increased our estimate for product returns as a result of returns of product lots related to the seven-day course of treatment of FACTIVE tablets. We believe the product returns were a result of a combination of the shift in product demand from seven-day course of treatment to five-day course of treatment and returns associated with initial stocking of FACTIVE. As of December 31, 2007 and 2006, our product return reserve was approximately \$3,169,000 and \$774,000, 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 in the consolidated balance sheets. As of December 31, 2007 and 2006, the balance of the cash discounts reserve was approximately \$343,000 and \$202,000, respectively.

#### *Rebates*

The liability for commercial managed care rebates is calculated based on historical and current rebate redemption and utilization rates with respect to each commercial contract. The liability for Medicaid rebates is calculated based on historical and current rebate redemption and utilization rates contractually submitted by each state. As of December 31, 2007 and 2006, the balance of the accrual for managed care and Medicaid rebates for ANTARA and FACTIVE in total was approximately \$4,263,000 and \$2,994,000, respectively. Considering the estimates made by us, as well as estimates reflected in third party utilization reports that are used in evaluating the required liability balance, we believe our estimates are reasonable. As of December 31, 2007, the significant change to our estimates in the periods presented is primarily attributable to the acquisition of the ANTARA product line.

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### *Special Promotional Programs*

From time to time, we offer certain promotional incentives to our customers for both ANTARA and FACTIVE and will continue this practice in the future. Such programs include: sample cards to retail consumers, certain product incentives to pharmacy customers, and other sales stocking allowances. We account for these programs in accordance with EITF No. 01-09, Accounting for Consideration Given by a Vendor to a Customer (EITFNo. 01-09). Examples of programs utilized to date are as follows:

#### *Voucher Rebate Programs for ANTARA*

Since acquiring ANTARA in August 2006, we have initiated three voucher rebate programs for ANTARA whereby we offered a point-of-sale rebate to retail consumers. The liabilities we recorded for these voucher rebate programs were estimated based upon the historical rebate redemption rates for similar completed programs by other pharmaceutical companies as reported to us by a third party claims processing organization. The first program expired on December 31, 2006, the second program expired on September 30, 2007, and the third program expires on February 28, 2009. As of December 31, 2007 and 2006, the balance of the liabilities for these voucher programs totaled approximately \$491,000 and \$619,000, respectively.

#### *Voucher Rebate Programs for FACTIVE*

We periodically initiate voucher rebate programs for FACTIVE whereby we offer mail-in rebates and point-of-sale rebates to retail consumers. The liabilities we record for these voucher rebate programs are estimated based upon the historical rebate redemption rates for similar completed programs. In April 2007, we initiated a voucher rebate program whereby we offered a point-of-sale rebate to retail consumers. This program expired on December 31, 2007. In October 2007, we initiated another voucher rebated program whereby we offered a point-of-sale rebate to retail consumers. This program expires on April 30, 2008. As of December 31, 2007 and 2006, the balance of the liabilities for these voucher programs totaled approximately \$1,396,000 and \$452,000, respectively.

### **Accounts Receivable**

Trade accounts receivable consists of amounts due from wholesalers for the purchase of ANTARA and FACTIVE. Ongoing credit evaluations of customers are performed and collateral is generally not required. As of December 31, 2007 and 2006, we reserved approximately \$35,000 and \$39,000, respectively, for bad debts related to the sale of ANTARA or FACTIVE. We continuously review all customer accounts to determine if an allowance for uncollectible accounts is necessary. We currently provide substantially all of our distributors with payment terms of up to 30 days on purchases of ANTARA and FACTIVE. Amounts past due from customers are determined based on contractual payment terms. Through December 31, 2007, payments have generally been made in a timely manner. We also reserved \$0 and \$310,000 as of December 31, 2007 and 2006, respectively, related to other non trade receivables.

### **Inventories**

Inventories are stated at the lower of cost or market value, with cost determined under the average cost method which approximates actual cost. Products are removed from inventory on a first-in-first-out basis and recognized as cost of goods sold on an average cost basis. For ANTARA, inventories consist of raw material and work-in-process of approximately \$2,363,000 and \$3,894,000 as of December 31, 2007 and 2006, respectively, and ANTARA finished capsules of approximately \$1,268,000 and \$1,027,000, as of December 31, 2007 and 2006, respectively. For FACTIVE, inventories consist of raw material in powder form and work-in-process of approximately \$3,505,000 and \$6,223,000 as of December 31, 2007 and 2006, respectively, and FACTIVE finished tablets of approximately \$1,923,000 and \$3,095,000, as of December 31, 2007 and 2006, respectively.

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On a quarterly basis, we analyze our inventory levels, and provide a reserve for 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 forecast requirements to cost of product revenues and marketing expense, respectively. During 2007, approximately \$1,204,000 of ANTARA inventory obtained in the product acquisition became obsolete and was expensed. Expired inventory is disposed of and the related costs are written off against the previously established reserves.

At December 31, 2007 and 2006, there was approximately \$1,088,000 and \$454,000 in ANTARA sample product to be used for ANTARA marketing programs and there was approximately \$655,000 and \$1,091,000 in FACTIVE sample product to be used for FACTIVE marketing programs. These are classified as other current assets in the consolidated balance sheets.

## **Long-Lived Assets**

We follow the provisions of Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS No. 144). Under SFAS No. 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 are each 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.

During 2007, events and circumstances, primarily a reduction in projected long-term cash flows, indicated that the FACTIVE intangible asset could become impaired. However, at December 31, 2007, our estimate of the undiscounted cash flows indicated that such carrying amounts are expected to be recovered and therefore, the assets are not impaired. Nonetheless, it is reasonably possible that the estimate of undiscounted cash flows may change in the near term resulting in the need to write down the intangible asset associated with FACTIVE to fair value. Our estimate of undiscounted cash flows is based upon several significant assumptions including, but not limited to, estimated domestic sales growth, the ability to significantly penetrate international markets and the ability to satisfy our minimum requirements under the agreement with the licensor, LG Life Sciences.

We also follow the provisions of SFAS No. 142, *Goodwill and Other Intangible Assets*, (SFAS No. 142). Under SFAS No. 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, 2007, we do not believe that any of our long-lived assets, goodwill, and other intangible assets are impaired.

## **Stock-Based Compensation**

Effective January 1, 2006, we adopted SFAS No. 123 (Revised 2004), *Share-Based Payment* (SFAS No. 123R) using the modified prospective transition method. SFAS No. 123R requires all share-based

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payments, including grants of stock options, to be recognized in the income statement as an operating expense, based on their fair values. The fair value of each option award is estimated on the grant date using the Black- Scholes-Merton option-pricing model. Our policy is to recognize compensation cost for awards with service conditions and graded vesting using the straight-line method. Additionally, our policy is to issue authorized but previously unissued shares to satisfy share option exercises, the issuance of restricted stock and stock issued under the Employee Stock Purchase Plan (ESPP). The amount of stock-based compensation recognized during a period is based on the value of the portion of the awards that are ultimately expected to vest. In addition, the requisite service period is generally equal to the vesting term.

Prior to January 1, 2006, we followed the provisions of SFAS No. 148, Accounting for Stock-Based Compensation, Transition and Disclosure (SFAS No. 148) and adopted the disclosure-only provisions of SFAS No. 123. In addition, we applied the intrinsic value method under Accounting Principles Board Opinion (APB) No. 25 Accounting for Stock Issued to Employees (APB No. 25) and related interpretations, in accounting for its stock-based compensation plans for awards to employees, rather than the alternative fair value accounting method provided for under SFAS No. 123.

### **Recent Accounting Pronouncements**

#### *Fair Value Measurements*

In September 2006, the FASB issued FASB Statement No. 157 Fair Value Measurements (SFAS No. 157). SFAS No. 157 establishes a common definition for fair value, creates a framework for measuring fair value, and expands disclosure requirements about such fair value measurements. SFAS No. 157 is effective for our first quarter of 2008. We are in the process of studying the impact of this interpretation on our financial accounting and reporting, however, we do not expect the adoption of SFAS No. 157 to have a material impact on our financial position or results of operations.

#### *Fair Value Option for Financial Assets and Financial Liabilities*

In February 2007, the FASB issued Statement No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115 (SFAS No. 159). SFAS No. 159 provides companies with an option to report selected financial assets and liabilities at fair value. Furthermore, SFAS No. 159 establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS No. 159 will be effective us beginning on January 1, 2008. We are currently evaluating the effect of SFAS No. 159 on our financial accounting and reporting, however, we do not expect the adoption of SFAS No. 159 to have a material impact on our financial position or results of operations.

#### *Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development*

In June 2007, the Emerging Issues Task Force issued EITF Issue 07-03, Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development (EITF No. 07-03). EITF No. 07-03 addresses the diversity which exists with respect to the accounting for the non-refundable portion of a payment made by a research and development entity for future research and development activities. Under EITF No. 07-03, an entity would defer and capitalize non-refundable advance payments made for research and development activities until the related goods are delivered or the related services are performed. EITF No. 07-03 is effective for fiscal years beginning after December 15, 2007 and interim periods within those years. We do not expect the adoption of EITF No. 07-03 to have a material impact on our financial position or results of operations.

#### *Accounting for Collaborative Arrangements*

In November 2007, the Emerging Issues Task Force issued EITF Issue 07-01 Accounting for Collaborative Arrangements (EITF No. 07-01). EITF No. 07-01 requires collaborators to present the results of activities for

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which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. Further, EITF No. 07-01 clarified that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to Issue 01-9, Accounting for Consideration Given by a Vendor to a Customer. EITF No. 07-01 is effective for fiscal years beginning after December 15, 2008. We have not yet completed our evaluation of EITF 07-01, but do not currently believe that it will have a material impact on the results of operations, financial position or cash flows.

## **RESULTS OF OPERATIONS**

### **Years Ended December 31, 2007 and 2006**

#### **Revenues**

Total net revenues increased 73% to \$79,969,000 for the year ended December 31, 2007 from \$46,152,000 for the year ended December 31, 2006.

Net product sales increased 105% to \$78,458,000 for the year ended December 31, 2007 from \$38,244,000 for the year ended December 31, 2006. This increase was primarily due to the promotion of ANTARA, which was acquired in August 2006, which resulted in a net increase of approximately \$41,793,000, partially offset by lower FACTIVE sales of approximately \$1,579,000 due to higher returns as a result in the shift of product demand from seven-day course of treatment to five-day course of treatment and returns associated with the initial stocking of FACTIVE.

Co-promotion revenue decreased 100% for the year ended December 31, 2007 from \$6,890,000 for the year ended December 31, 2006 due to the termination of the co-promotion arrangement with Auxilium in August 2006.

Other revenues increased 48% to \$1,511,000 for the year ended December 31, 2007 from \$1,018,000 for the year ended December 31, 2006, primarily due to recognition of a milestone achievement of \$1,000,000 from Abbott Laboratories, Ltd., (Abbott Canada) the Canadian Affiliate of Abbott, relating to the approval to sell FACTIVE tablets in Canada as well as the amortization of upfront license fees from our agreements with Pfizer Mexico and Menarini. We do not believe that other revenues will be a significant contributor to revenues in the future.

#### **Costs and Expenses**

Total costs and expenses decreased slightly to \$117,965,000 for the year ended December 31, 2007 from \$118,071,000 for the year ended December 31, 2006.

Cost of product sales increased 59% to approximately \$31,269,000 in 2007 from \$19,613,000 in 2006 as a result of increased product costs of approximately \$11,656,000 associated with an increase in shipments of ANTARA capsules. Our overall gross product margin for the year ended December 31, 2007 and 2006 was 60% and 49%, respectively. The increase in gross margin is the result of an increase in shipments for ANTARA capsules offset by higher returns of FACTIVE tablets associated with the combination of the shift in product demand from seven day course of treatment to five day course of treatment and returns associated with initial stocking of FACTIVE. Additionally, in 2007, we recorded approximately \$1,296,000 of obsolete inventory related to the initial product obtained upon the acquisition of ANTARA and also recorded approximately \$471,000 related to a minimum royalty obligation to Ethypharm. In addition, included in the cost of product sales is approximately \$4,767,000 of amortization of intangible assets associated with FACTIVE for each of the years

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ended December 31, 2007 and 2006 and approximately \$4,341,000 and \$1,447,000, respectively, of amortization of intangible assets associated with ANTARA for each of the years ended December 31, 2007 and 2006.

Research and development expenses decreased 53% to \$5,845,000 in 2007 from \$12,406,000 in 2006. This decrease is primarily due to the completion of the FACTIVE five-day treatment of CAP trial in 2006 and the completion of the enrollment of the 7,500 patients in the FACTIVE post-marketing trials in February 2007. Our total costs related to this clinical trial were completed by the end of the second quarter of 2007. At December 31, 2007, there was no clinical trial accrual balance remaining and we do not believe there will be significant costs associated with clinical trials in the immediate future.

Selling and marketing expenses decreased slightly to \$66,278,000 in 2007 from \$69,211,000 in 2006. This decrease is a result of decreases in co-promotion expenses relative to our arrangement with Auxilium which terminated in 2006 of approximately \$2,482,000 along with overall cost control efforts during the year ended December 31, 2007 resulting in lower conference and meeting expenses of approximately \$667,000, and lower publication, media, and market research costs of approximately \$712,000. The decrease was also attributable to decreases in payroll and payroll-related costs of approximately \$610,000 and stock-based compensation costs of approximately \$263,000, offset by increases in other selling and marketing expenses of approximately \$683,000 and costs associated with travel and entertainment of approximately \$1,118,000 related to sales personnel.

General and administrative expenses decreased 13% to approximately \$14,573,000 in 2007 from approximately \$16,841,000 in 2006. This decrease is a result a decrease in technology license fees of approximately \$1,250,000, as well as overall cost control efforts during 2007 which resulted in decreases in payroll and payroll related costs of approximately \$317,000, decreases in stock-based compensation expense of approximately \$788,000, as well as decreases in other general and administrative expenses of approximately \$573,000. These decreases were partially offset by an increase in legal fees and settlement costs associated with a legal dispute.

**Other Income and Expense**

Interest income decreased 15% to approximately \$2,541,000 in 2007 from approximately \$2,995,000 in 2006 reflecting higher yields on cash balances in 2007, offset by lower overall cash balances in 2007.

Interest expense significantly increased 155% to approximately \$28,206,000 in 2007 from approximately \$11,056,000 in 2006. For the year ended 2007, interest expense imputed using the effective interest rate method primarily consisted of approximately \$10,645,000 related to financing with Paul Capital, approximately \$7,649,000 due to accretion of the bond discount associated with newly exchanged debt, approximately \$5,331,000 related to approximately \$225,666,000 of 3.50% convertible senior notes, resulting from the exchange of previously-outstanding 3 1/2 % convertible promissory notes, exchange of previously outstanding 5% convertible promissory notes and issuance of new notes in May of 2007. Additionally, interest expense included approximately \$1,787,000 related to approximately \$152,700,000 of 3 1/2 % senior convertible promissory notes issued in the second quarter of 2004, of which approximately \$829,000 remains after the debt exchange completed in May 2007, approximately \$954,000 related to approximately \$22,310,000 of 5% convertible promissory notes assumed in the Genesoft merger, of which approximately \$13,300,000 remains after the debt exchange completed in May 2007, approximately \$1,325,000 related to amortization of deferred financing costs, as well as approximately \$515,000 of non-cash interest expense related to the facility lease liability.

Gain on disposition of investment for year ended December 31, 2007 of approximately \$231,000 resulted from milestones achieved by Agencourt Biosciences. The gain on disposition of investment of approximately \$1,617,000 for year ended December 31, 2006 resulted from the sale of our investment in Agencourt Biosciences.

We recorded a one-time non cash gain on exchange of convertible notes of approximately \$30,824,000 in the year ended December 31, 2007 resulting from the issuance of approximately \$225,666,000 of 3.50%

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convertible senior notes due 2011 in connection with the exchange and tender of approximately \$151,921,000 of our previously-outstanding 3 1/2% senior convertible promissory notes due 2011 and the exchange and tender of approximately \$9,010,000 of our previously outstanding 5% convertible promissory notes due 2009. The gain arose due to the fact that fair value of the previously outstanding 3 1/2% senior convertible promissory notes exceeded that of the newly issued 3.50% convertible senior notes.

Gain on derivative related to convertible notes was approximately \$3,023,000 for the year ended December 31, 2007. This gain consists of a non-cash gain resulting from changes in the fair value of the interest make-whole derivative included in our 3.50% convertible senior notes due 2011 which were issued in May 2007 of approximately \$3,004,000 and also approximately \$19,000, related to a gain from changes in the fair value of derivative related to the financing associated with the acquisition of ANTARA issued in August 2006.

### **Years Ended December 31, 2006 and 2005**

#### **Revenues**

Total net revenues increased 95% to \$46,152,000 for the year ended December 31, 2006 from \$23,609,000 for the year ended December 31, 2005.

Net product sales increased 87% to \$38,244,000 for the year ended December 31, 2006 from \$20,458,000 for the year ended December 31, 2005. This increase was primarily related to the acquisition of ANTARA 130 mg (fenofibrate) capsules in August 2006 which resulted in approximately \$16,778,000 in net product sales and increased shipments of FACTIVE tablets of approximately \$1,008,000.

Co-promotion revenue increased 133% to \$6,890,000 for the year ended December 31, 2006 from \$2,954,000 for the year ended December 31, 2005, primarily due to the initiation of our co-promotion of TESTIM in May 2005, higher gross profits related to increased TESTIM prescriptions in 2006 and also due to a \$1,800,000 payment from Auxilium Pharmaceuticals in August 2006 in connection with the termination of the co-promotion arrangement.

Other revenues increased significantly to \$1,018,000 for the year ended December 31, 2006 from \$197,000 for the year ended December 31, 2005, primarily due to the recognition of revenues in connection with various milestone achievements related to Pfizer Mexico upon the regulatory approval to distribute and sell FACTIVE tablets in Mexico and an up-front payment from Pfizer Mexico which is recognized over the term of our obligation under the agreement. We expect our revenues related to both the biopharmaceutical alliances and genomics services to be minimal in the future.

#### **Costs and Expenses**

Total costs and expenses increased 5% to \$118,071,000 for the year ended December 31, 2006 from \$112,281,000 in 2005, primarily due to cost of product sales associated with the acquisition of ANTARA during 2006.

Cost of product sales increased 100% to approximately \$19,613,000 in 2006 from \$9,830,000 in 2005 as a result of increased product costs of approximately \$5,040,000 associated with an increase in shipments of ANTARA capsules as a result of our product acquisition of ANTARA in August 2006. Our overall gross product margin for the year ended December 31, 2006 and 2005 was 49% and 52%, respectively. The primary reason for the decrease in margin was due to approximately \$1,700,000 associated with obsolete inventory in 2006 and costs associated with the write-up of inventory to fair value of ANTARA product obtained during the acquisition of the product line. In addition, included in the cost of product sales is approximately \$4,767,000 of amortization of intangible assets associated with FACTIVE for each of the years ended December 31, 2006 and 2005 and approximately \$1,610,000 of amortization of intangible assets associated with ANTARA for the year ended December 31, 2006.

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Research and development expenses decreased 14% to \$12,406,000 in 2006 from \$14,432,000 in 2005. Research and development activities include clinical trials, other clinical development, technology transfer and process optimization for manufacturing. These research and development expenses primarily consist of salaries and related expenses for personnel 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 is due to the completion of the FACTIVE five-day clinical trial and also a decrease in the costs primarily related to external costs and materials associated with the FACTIVE post-marketing study as the trial approaches near completion in the first half of 2007. We expect research and development expense to continue to decrease in 2007 as the FACTIVE post-marketing study is expected to be completed in the first half of 2007.

Selling and marketing expenses decreased 8% to \$69,211,000 in 2006 from \$74,931,000 in 2005. This decrease was primarily due to expenses in 2005 being unusually high related to hiring additional sales and marketing personnel costs of \$5,751,000, increased other marketing, advertising and promotional costs of approximately \$3,081,000 to support the marketing efforts for FACTIVE, offset by increased marketing costs associated with the promotion of ANTARA in August 2006 of approximately \$943,000 and increased costs in 2006 of \$2,169,000 associated with the promotion of TESTIM which began in the second quarter of 2005 and was terminated in August 2006.

General and administrative expenses increased 29% to \$16,841,000 in 2006 from \$13,088,000 in 2005 primarily due to an increase in general and administrative payroll and related costs of approximately \$1,472,000, an increase in stock based compensation due to the adoption of SFAS No. 123R of approximately \$2,267,000, an increase in legal fees of approximately \$400,000 and an increase in general and administrative expenses of approximately \$58,000 offset by a decrease in technology license fees of approximately \$444,000.

### **Other Income and Expense**

Interest income decreased 12% to approximately \$2,995,000 in 2006 from approximately \$3,400,000 in 2005 reflecting higher yields on cash balances in 2006, offset by lower overall cash balances in 2006.

Interest expense significantly increased 36% to approximately \$11,056,000 in 2006 from approximately \$8,126,000 in 2005. In 2006, 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, \$2,987,000 related to financing with Paul Capital, approximately \$1,241,000 related to the issuance of \$22.0 million of convertible notes in connection with the GeneSoft merger, \$827,000 related to amortization of deferred financing costs along with approximately \$640,000 related to non-cash interest expense related to the facility lease liability.

For the year ended December 31, 2005, we recorded a gain from the sale of intellectual property of \$2,500,000, from the sale of intellectual property related to the genomic sequence of an undisclosed pathogen to Wyeth.

For the year ended December 31, 2006, we recorded a gain on the disposition of an investment of approximately \$1,617,000 in exchange for our shares in Agencourt Personal Genomics Bioscience related to the merger with Applera Corporation. For the year ended December 31, 2005 we 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 acquired by Beckman Coulter in a cash transaction.

### **Liquidity and Capital Resources**

Our primary sources of cash have been from the sale of debt and equity securities, the sale of ANTARA capsules and FACTIVE tablets and co-promotion revenues based on the sale of TESTIM. The TESTIM co-promotion agreement was terminated on August 31, 2006.



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As of December 31, 2007, we had total cash, cash equivalents and restricted cash of approximately \$52,466,000, which includes approximately \$4,198,000 in restricted cash. We will need to raise additional capital in the future to fund our operations. We believe that, under our current rate of investment in development and commercialization programs, our existing capital resources are adequate to support operations through at least the end of 2008. There is no assurance, however, that changes in our plans or events affecting our operations will not result in accelerated or unexpected expenditures.

In recent years, we have experienced significant hiring and employment costs in an effort to build an effective sales and marketing organization to commercialize our products, expand the medical/development organization to support additional development and commercialization of our products and to build the infrastructure necessary to support these efforts. We expect expenses in the sales and marketing areas to reflect continued commercialization of ANTARA and FACTIVE as we seek to grow our sales.

*Cash Flows*

Our operating activities used cash of approximately \$34,661,000, \$63,635,000 and \$96,880,000 in 2007, 2006 and 2005, respectively.

Cash used in our operating activities for 2007 was primarily a result of our net loss of approximately \$29,853,000 along with non-cash items such as a non-cash gain on exchange of convertible note of approximately \$30,824,000, non-cash depreciation and amortization expenses of approximately \$9,847,000, non-cash interest expenses of approximately \$9,623,000, a non-cash gain from the change in the fair value of derivatives of approximately \$3,023,000, stock-based compensation of approximately \$2,713,000, and provision for excess and obsolete inventories of approximately \$793,000. Additionally, cash used in our operating activities includes an increase of approximately \$2,922,000 in accounts receivable due to higher shipments of ANTARA capsules and FACTIVE tablets and an increase in prepaid and other current assets of approximately \$96,000 along with decreases in accounts payable of approximately \$141,000 as a result of timing of vendor payments, decreases in accrued facilities impairment charges of approximately \$2,618,000 related to our west coast facility, recovery of bad debt of approximately \$172,000, a gain on disposition of investment of approximately \$231,000, as well as decreases in deferred revenue of approximately \$750,000 as a result of the amortization of upfront license fees from our agreements with Pfizer Mexico and Menarini.

These uses of cash were partially offset by increases in accrued expenses and other liabilities of approximately \$4,915,000 relating to timing of vendor invoices, decreases in inventory of approximately \$4,386,000 as a result of increased sales of ANTARA, as well as increases in other long-term liabilities of approximately \$3,692,000 related to accrued interest on long-term debt.

Cash used in our operating activities for 2006 was primarily a result of our net loss of approximately \$78,477,000, adjusted for the gains of approximately \$1,617,000 on the disposition of investment, an increase in inventories of approximately \$1,796,000 due to increased demand of ANTARA capsules and FACTIVE tablets, and an increase in accounts receivable of approximately \$6,080,000 as a result of the acquisition of ANTARA, as well as decreases in accrued facilities impairment charge of approximately \$2,826,000 related to our west coast facility.

These uses of cash were partially offset by decreases in prepaid expenses and other current assets of approximately \$2,134,000 resulting from decreases in net samples inventory and decreased costs associated with the utilization of a contracted third party sales organization, as well as, increases in accounts payable of approximately \$3,955,000 primarily resulting from the acquisition of ANTARA, including royalties payable on the net sales of ANTARA and FACTIVE sold in the U.S. and accounts payable and other accrued expenses acquired as part of the ANTARA acquisition. Additional offsets include increases in accrued expenses and other current liabilities of approximately \$3,335,000 resulting primarily from increases in sales reserves and allowances and royalty interest payable as a result of the acquisition of ANTARA, increases in deferred revenue of approximately \$1,386,000 pertaining to up-front license fees in relation to sublicense agreements with Pfizer

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Mexico, Abbott Canada, and Menarini, increases in other long-term liabilities of approximately \$1,869,000 resulting from accrued interest on the \$22.0 million convertible note and the \$20.0 million note payable to Paul Capital, as well as non-cash items such as depreciation and amortization expenses which includes amortization of intangible assets, stock based compensation, and non-cash interest expense of approximately \$12,502,000 as well as provision for excess and obsolete inventories and provision for accounts receivables of approximately \$1,980,000.

Cash used in our operating activities for 2005 was primarily a result of our net loss of approximately \$88,593,000, adjusted for the gains of approximately \$2,162,000 on the disposition of investment, 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 resulting from the co-promotion agreement with Auxillium, as well as decreases in accounts payable of approximately \$2,633,000 resulting from timing of payables processing, accrued expenses and other liabilities of approximately \$6,762,000 resulting primarily from decreases in costs associated with the GeneSoft merger and decreases in costs associated with the utilization of a contracted third party sales organization, deferred revenue of approximately \$1,302,000 related to our initial stocking incentive program, and accrued facilities impairment charge of approximately \$2,947,000 related to our west coast facility.

These uses of cash were partially offset by decreases in prepaid expenses and other current assets of approximately \$6,597,000 primarily resulting from the expiration of our contract with a contracted third party sales representative provider and decreases in accrued other long-term liabilities of approximately \$993,000 resulting from accrued interest on the \$22.0 million convertible note, as well as non-cash items such as depreciation and amortization expenses including amortization of intangible assets, stock based compensation, non-cash interest expense of approximately 7,974,000 as well as provision for excess and obsolete inventories of approximately \$1,067,000.

Our investing activities provided cash of approximately \$3,906,000 in 2007, used cash of approximately \$68,119,000 in 2006 and provided cash of approximately \$96,758,000 in 2005.

Our investing activities provided cash of approximately \$3,906,000 in 2007 primarily related to a decrease of approximately \$2,414,000 in restricted cash, proceeds from notes receivable of approximately \$1,373,000 and proceeds from the disposition of investment of approximately \$231,000. These cash proceeds were partially offset by an increase in other assets of approximately \$63,000.

Cash used in our investing activities in 2006 were primarily related to the acquisition of ANTARA of approximately \$77,563,000, and increases in other assets of approximately \$329,000 and net purchases of property and equipment of approximately \$263,000. These uses of cash were partially offset by proceeds from maturities of marketable securities of approximately \$2,696,000, decreases in restricted cash associated with interest payments on debt of approximately \$5,118,000, proceeds from the disposition of an investment of approximately \$1,617,000 and net proceeds from notes receivable of approximately \$604,000.

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 \$294,000 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.

Our financing activities provided cash of approximately \$40,827,000 in 2007 primarily due to the net proceeds from the issuance of new notes in May 2007 of approximately \$40,444,000, exercise of 4,980 stock options for approximately \$17,000, and proceeds from the issuance of 95,045 shares of stock under the employee stock purchase plan of approximately \$404,000, offset by payments on long-term obligation of approximately \$38,000.

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Our financing activities provided cash of approximately \$104,332,000 in 2006. This was primarily due to the issuance of 2,254,402 shares of common stock in connection with the completion of a private placement which generated net proceeds of approximately \$33,477,000; proceeds of \$20,000,000 from the issuance of a note in connection with the financing of the ANTARA acquisition; proceeds of \$40,000,000 from an assignment of revenue interest in connection with the financing of the ANTARA acquisition and net proceeds of approximately \$9,958,000 from the issuance of 1,388,889 shares of common stock in connection with financing the acquisition of ANTARA. In addition, we received approximately \$166,000 from the exercise of 89,456 stock options and proceeds of approximately \$740,000 from the issuance of 78,987 shares of stock under the employee stock purchase plan, offset by payments made on capital lease obligations of approximately \$9,000.

Our financing activities in 2005 provided cash of approximately \$997,000, 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.

At December 31, 2007, we had net operating loss carryforwards of approximately \$457,708,000 and \$319,468,000 available to reduce federal and state taxable income, if any, respectively. We also had tax research credit carryforwards of approximately \$17,343,000 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*

On February 6, 2004, in connection with our merger with GeneSoft, we issued approximately \$22,310,000 in principal amount of our 5% convertible five year promissory notes due February 2009 (the 2009 Notes ). Following the exchange offer completed in May 2007 described below, there are approximately \$13,300,000 million principal amount of the 2009 Notes outstanding at December 31, 2007. The 2009 Notes are convertible into our common stock at the option of the holders, at a conversion price of \$53.13 per share, as adjusted pursuant to the reverse stock split which we effectuated in November 2006.

In the quarter ended June 26, 2004, we issued \$152,750,000 in principal amount of our 3 1/2% senior convertible promissory notes due in April 2011 (the Original 2011 Notes ). Following the exchange offer completed in May 2007 described below, there are approximately \$829,000 principal amount of the Original 2011 Notes outstanding at December 31, 2007. These notes are convertible into our common stock at the option of the holders at a conversion price of \$53.14 per share, as adjusted pursuant to the reverse stock split which we effectuated in November 2006. We may not redeem the outstanding Original 2011 Notes at our election before May 10, 2010. After this date, we can redeem all or a part of the Original 2011 for cash at a price equal to 100% of the principal amount of the notes to be redeemed plus accrued and unpaid interest. The holders' right of repurchase under the Original 2011 Notes is identical to the right of repurchase under the New Notes (defined below) and is described below.

In May 2007, we completed (i) an exchange offer with certain holders of the Original 2011 Notes in which we exchanged \$151,921,000 aggregate principal amount of our new 3.50% Convertible Senior Notes due 2011 (the New Notes ) for \$151,921,000 aggregate principal amount of our then outstanding Original 2011 Notes; and (ii) an exchange offer with holders of the 2009 Notes in which we exchanged approximately \$10,574,000 aggregate principal and accrued interest amount of our then outstanding 2009 Notes for approximately \$13,746,000 aggregate principal amounts of the New Notes. We also issued an additional \$60,000,000 of New Notes to the public for cash at a public offering price of 77.5% of principal resulting in \$46,500,000 in gross proceeds to us.

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The New Notes are initially convertible into approximately 16,718,000 common shares at a conversion rate of 74.074 of our common shares per \$1,000 principal amount of New Notes, which is equivalent to a conversion price of approximately \$13.50 per common share. The New Notes are convertible at any time by the holder. In the event of a fundamental change, holders of the Original 2011 Notes and the New 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. Under the indenture for the Original 2011 Notes and the New Notes a fundamental change will be deemed to occur if (i) a change of control transaction occurs in which substantially all of our common stock is exchanged either for consideration other than common stock that is listed on a U.S. national securities exchange or is exchanged for consideration other than common stock that is approved for quotation on a U.S. system of automated dissemination of quotations of securities or (ii) our common stock is neither listed for trading on a U.S. national securities exchange nor approved for listing on any U.S. system of automated dissemination of quotations of securities prices.

Before May 10, 2010, we may not redeem the New Notes. On or after May 10, 2010, we may redeem any or all of the New Notes at 100% of the principal amount, plus accrued and unpaid interest. In addition, we may automatically convert some or all of the New Notes on or prior to the maturity date if the closing price of its common shares has exceeded 130% of the conversion price then in effect for at least 20 trading days during any consecutive 30 trading day period ending within five trading days prior to the notice of auto-conversion (the auto-conversion feature). If a holder elects to voluntarily convert their New Notes or we elect to automatically convert some or all of the New Notes on or prior to May 10, 2010, we will pay additional interest to holders of New Notes being converted. This additional interest will be equal to the amount of interest that would have been payable on the New Notes from the last day interest was paid on the New Notes, through and including May 10, 2010. Additional interest, if any, will be paid in cash or in our common shares, at our option. If we pay additional interest upon a voluntary conversion with our common shares, such shares will be valued at the conversion price that is in effect at that time. If we pay additional interest upon an automatic conversion with our common shares, such shares will be valued at 90% of the automatic conversion price that is in effect at that time.

We have accounted for the New Notes in accordance with the guidance as set forth in EITF No. 96-19, Debtor's Accounting for a Modification or Exchange of Debt Instruments (EITF No. 96-19), SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities, as amended (SFAS No. 133), EITF No. 05-7, Accounting for Modifications to Conversion Options Embedded in Debt Instruments and Related Issues (EITF No. 05-7), EITF No. 00-19, Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock (EITF No. 00-19), EITF No. 05-02, Meaning of Conventional Convertible Debt Instrument (EITF No. 05-02) and EITF No. 01-6, The Meaning of Indexed to a Company's Own Stock (EITF No. 01-6), and determined that the exchange represents an extinguishment of existing debt rather than a modification. We recorded a gain of approximately \$30,824,000 upon the extinguishment of debt, which was a result of exchanging a majority of the Original 2011 Notes and a portion of the 2009 Notes that were issued at par value, for the New Notes that were issued at 77.5% of par (i.e. a 22.5% discount). The gain arose due to the fact that the fair value of the Original 2011 Notes exceeded that of the New Notes. The debt issuance costs related to the Original 2011 Notes in the amount of approximately \$3,285,000 are netted against the gain.

The additional interest payment described above, which may be issued upon conversion, is considered an embedded derivative under SFAS No. 133 and requires bifurcation from the host debt. We also considered the provisions of EITF No. 05-2, and concluded that this is not conventional convertible debt.

In accordance with SFAS No. 133, we have separately accounted for the additional interest payment feature of the New Notes as an embedded derivative instrument, which is measured at fair value and classified on the consolidated balance sheets as other long term liabilities. Changes in the fair value of the embedded derivative are recognized in earnings. The derivative liability is revalued quarterly and changes in the fair value through either the date the additional interest payment provisions expire, at which the liability will be zero, or the date at which the additional interest payment provision is triggered, are recorded as other expense or income. For the purpose of accounting for the New Notes issued in the exchange offer, the fair value of the embedded derivative

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upon issuance was subtracted from the carrying value of the debt and reflected as a debt discount. The debt discount is amortized as interest expense using the effective interest method through the date the notes are scheduled to mature.

Convertible debt upon the exchange and new offering on May 1, 2007 consisted of the following (in thousands):

3.50 % Convertible senior notes	\$ 225,692
Discount on convertible notes	(50,781)
Embedded derivative	(3,077)
Total	\$ 171,834

The additional New Notes generated gross proceeds of \$46,500,000. Debt issuance costs, related to the New Notes, of approximately \$6,057,000 are being amortized to interest expense, on a straight-line basis over the 48 month period to maturity of the notes. As of December 31, 2007, the fair value of the derivative is approximately \$73,000 which reflects a change in the fair value of approximately \$3,004,000 which is included as gain on derivative in the consolidated statements of operations.

For the year ended December 31, 2007, we incurred approximately \$8,071,000 in interest expense on our convertible debt, which is payable on a semi-annual basis. Additionally, we amortized approximately \$7,649,000 as non-cash interest expense related to the accretion of the bond discount and approximately \$1,325,000 in new debt issuance costs.

*Other Financial Arrangements*

To finance the acquisition of ANTARA in August 2006, we, together with our wholly-owned subsidiary Guardian II Acquisition Corporation, or Guardian II (the entity which holds all of the ANTARA assets), entered into several financing agreements with Paul Royalty Fund Holdings II, LP, an affiliate of Paul Capital Partners, or Paul Capital, including the Revenue Interests Assignment Agreement, the Note Purchase Agreement and the Common Stock and Warrant Purchase Agreement, in consideration for an aggregate amount of \$70 million.

Under the Revenue Interests Assignment Agreement (the Revenue Agreement), we sold to Paul Capital the right to receive specified royalties on our net sales in the United States (and the net sales of its affiliates and licensees) of FACTIVE tablets and Guardian II sold to Paul Capital the right to receive specified royalties on Guardian II's net sales in the United States (and the net sales of its respective affiliates and licensees) of the ANTARA products, in each case until December 31, 2016. The royalty payable to Paul Capital on net sales of ANTARA capsules and FACTIVE tablets starts each fiscal year as a high single-digit royalty rate and could decline to a low single-digit royalty rate based on achievement of annual specified sales thresholds in each fiscal year. Once the cumulative royalty payments to Paul Capital exceed \$100 million, the royalties become nominal.

In connection with the Revenue Agreement, we recorded a liability, referred to as the revenue interest liability, of approximately \$40,000,000 in accordance with EITF No. 88-18, Sales of Future Revenues (EITF No. 88-18). We will impute interest expense associated with this liability using the effective interest rate method and will record a corresponding accrued interest liability. The effective interest rate is calculated based on the rate that would enable the debt to be repaid in full over the life of the arrangement. The interest rate on this liability may vary during the term of the agreement depending on a number of factors, including the level of ANTARA and FACTIVE sales. Payments made to Paul Capital as a result of ANTARA and FACTIVE sales levels will reduce the accrued interest liability and the principal amount of the revenue interest liability. Through December 31, 2007, there have been no principal payments made to Paul Capital as a result of ANTARA or FACTIVE sales.

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In the event of (i) a change of control of Oscient or Guardian II, (ii) a bankruptcy of Oscient or Guardian II, (iii) a transfer by Oscient or any of its subsidiaries of substantially all of either ANTARA or FACTIVE, (iv) subject to a cure period, breach of certain material covenants and representations in the Revenue Agreement and (v) in the event the sale of ANTARA is suspended due to a court issued injunction or we elect to suspend sales of ANTARA, in each case as a result of a lawsuit by certain third parties (each a Put Event), Paul Capital has the right to require Oscient and Guardian II to repurchase from Paul Capital its royalty interest at a price in cash which equals the greater of (a) a specified multiple of cumulative payments made by Paul Capital under the Revenue Agreement less the cumulative royalties previously paid to Paul Capital; or (b) the amount which will provide Paul Capital, when taken together with the royalties previously paid, a specified rate of return (the Put/Call Price). Upon a bankruptcy event, Oscient and Guardian II are automatically required to repurchase the Paul Capital royalty interest at the Put/Call Price. In the event of a change of control of Oscient, we have the right to repurchase the Paul Capital royalty interest for an amount equal to the Put/Call Price. We have determined that Paul Capital's put option and our call option meet the criteria to be considered an embedded derivative and should be accounted for as such. We recorded a net liability of \$1,005,000 related to the put/call option to reflect its estimated fair value as of the date of the agreement, in accordance with SFAS No. 133. This liability is revalued on a quarterly basis to reflect any changes in the fair value and any gain or loss resulting from the revaluation will be recorded in earnings. As of December 31, 2007, the fair value of the derivative is approximately \$986,000 which reflects a change in the fair value of approximately \$19,000 which has been recorded as a gain on derivative in the consolidated statements of operations.

During the first two fiscal years immediately following the fiscal year in which combined annual net sales of ANTARA and FACTIVE are equal to or greater than \$125 million, Oscient and Guardian II have the right, but not the obligation, to reduce the royalty percentages due under the Revenue Agreement to Paul Capital by 50% by paying Paul Capital a price in cash which will provide Paul Capital, when taken together with the royalties previously paid, a specified rate of return. During the first two fiscal years immediately following the fiscal year in which combined annual net sales of ANTARA and FACTIVE are equal to or greater than \$250 million, Oscient and Guardian II have the right, but not the obligation, to repurchase the Paul Capital royalty interest at a price in cash which will provide Paul Capital, when taken together with the royalties previously paid, a specified rate of return.

Guardian II entered into a Note Purchase Agreement, or the Note Purchase Agreement, with Paul Capital pursuant to which Guardian II issued and sold a \$20,000,000 aggregate principal amount of 12% senior secured note, or the Note, due on the fourth anniversary of the closing date, subject to Guardian II's option to extend the maturity to the sixth anniversary of the closing date, provided (i) there are no defaults under the Note at the time, and (ii) we issue to Paul Capital, at the time of the exercise of such option, a warrant for a number of shares of common stock equal to 10% of the principal balance plus accrued interest divided by \$6.94, with an exercise price of \$6.94 per share. If we exercise such option, the number of shares subject to the warrant issuable to Paul Capital would be between 288,018 shares and 367,529 shares, depending upon the amount, if any, of the interest payable on the Note we elect to have added to the principal of the Note rather than paid in cash as described below.

Interest is payable semi-annually in arrears on the last day of each of March and September. Guardian II has the option to pay interest in cash or to have 50% of the interest paid in cash and 50% of the interest added to principal. In the event of a change of control of Oscient or on or after the second anniversary of the closing, Oscient and Guardian II may at our option prepay all or any part of the Note at a premium which declines over time. In the event of an event of default, with event of default defined as a continuing Put Event under the Revenue Agreement as described in more detail above, the outstanding principal and interest in the Note will become immediately due and payable. As of December 31, 2007, we exercised our option to add approximately \$1,694,000 of interest expense payable to the principal of the Note.

Subject to the Revenue Agreement and the Note Purchase Agreement, without the prior written consent of Paul Capital, Oscient and Guardian II have agreed not to (i) amend, waive any rights under, or terminate any material license agreements, including the agreements relating to the ANTARA products and FACTIVE,

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(ii) enter into any new agreement or amend or fail to exercise any of its material rights under existing agreements that would adversely affect Paul Capital's royalty interest, and (iii) sell any material assets related to ANTARA or FACTIVE.

Pursuant to the terms of the Revenue Agreement and the Note Purchase Agreement, Guardian II and Paul Capital entered into a Security Agreement, or the Security Agreement, under which Guardian II granted to Paul Capital a security interest in and to substantially all assets owned by Guardian II (including rights to the ANTARA products) in order to secure its performance under each of the Revenue Agreement, the Note Purchase Agreement and the Note. To the extent the indebtedness under certain of our pre-existing debt obligations is refinanced or replaced and such replacement or refinancing indebtedness is secured, we have agreed to equally and ratably secure its obligations under the Revenue Agreement.

As part of the financing, we and Paul Capital also entered into a Common Stock and Warrant Purchase Agreement, or the Stock and Warrant Purchase Agreement, pursuant to which, in exchange for \$10 million, Oscient sold to Paul Capital 1,388,889 shares (the Shares) of the Common Stock, at a price of \$7.20 per share (the Private Placement) and issued Paul Capital a warrant (the Warrant) to purchase 288,018 shares of Common Stock (the Warrant Shares) at an exercise price of \$6.94 per share. The Warrant is exercisable for seven years from the date of closing. The Warrant contains a net share settlement feature and penalties if Oscient does not deliver the applicable amount of Warrant Shares within three trading days of exercise of a Warrant by Paul Capital. The Warrant also contains provisions providing that, at Paul Capital's election, Oscient must re-purchase the Warrant from Paul Capital upon a sale of the Company in which the consideration for such sale is solely cash. The warrant has not been exercised as of December 31, 2007. We agreed, pursuant to the Stock and Warrant Purchase Agreement, to elect one person designated by Paul Capital to our Board of Directors following the closing and to continue to nominate one person designated by Paul Capital for election to our Board of Directors by our shareholders. The director designated by Paul Capital shall resign and we shall no longer be required to nominate a director designated by Paul Capital upon the later of the following events: (1) if Paul Capital ceases to own at least five percent of the our Common Stock or securities convertible into our Common Stock; (2) if we owe Paul Capital less than \$5,000,000 under the Note pursuant to the Note Purchase Agreement; (3) the cumulative payments to Paul Capital made by us under the terms of the Revenue Agreement first exceed 250% of the consideration paid to us by Paul Capital; or (4) if the amounts due by us pursuant to the Revenue Agreement cease to be due. If at any time Paul Capital's designee is not elected to our Board of Directors, Paul Capital's designee will have a right to participate in all meetings of our Board of Directors in a nonvoting observer capacity.

**Contractual Obligations**

Our major outstanding contractual obligations relate to our convertible promissory notes, our facility leases and our financing agreements with Paul Royalty Fund Holdings II, LP, through which we funded our acquisition of ANTARA. 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).

	2008	2009	2010	2011	2012	Thereafter	Total
Operating leases	\$ 5,544	\$ 5,822	\$ 6,014	\$ 2,005	\$ 469	\$ 19	\$ 19,873
Sublease contracted income	(2,795)	(746)	(716)	(122)			(4,379)
Current sublease forecasts (a)		(500)	(563)	(96)			(1,159)
	2,749	4,576	4,735	1,787	469	19	14,335
Convertible promissory notes, including interest (b,c)	7,927	24,952	7,927	228,803			271,265
Term Loan (d)	1,321	1,402	26,625				29,348
Total forecasted contractual obligations	\$ 11,997	\$ 30,930	\$ 39,287	\$ 230,590	\$ 469	\$ 19	\$ 314,948

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

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- (b) Upon the closing of the convertible debt exchange in May 2007, we exchanged approximately \$9.0 million of GeneSoft promissory notes plus accrued interest of approximately \$1.6 million for approximately \$13.7 million of 3.5% senior convertible promissory notes due in April 2011. Approximately \$13.3 million plus accrued interest of the original GeneSoft promissory notes remain outstanding and are due February 9, 2009
- (c) In the quarter ended June 30, 2007, we issued \$60 million in principal amount of 3.5% senior convertible promissory notes due in April 2011 and also refinanced approximately \$151.9 in principal amount of 3 1/2% senior convertible promissory notes due in April 2011. These notes are convertible into shares of our common stock at the option of the holders at a conversion price of \$13.50 per share. In connection with the issuance, we recorded deferred financing costs of approximately \$6.1 million which is being amortized to interest expense on a straight-line basis over the period the notes are outstanding.
- (d) Pursuant to the financing of our acquisition of ANTARA, our wholly owned subsidiary, Guardian II Acquisition Corporation, entered into a Note Purchase Agreement with Paul Capital pursuant to which Guardian II issued and sold a \$20.0 million aggregate principal amount of 12% senior secured note due on the fourth anniversary of the closing date, subject to Guardian II's option to extend the maturity to the sixth anniversary of the closing date. Interest is payable semi-annually in arrears on the last day of each of March and September. Guardian II has the option to pay interest in cash or to have 50% of the interest paid in cash and 50% of the interest added to principal.
- (e) The above contractual obligation table excludes amounts payable to Paul Capital in relation to the Revenue Interest Agreement. In addition to the amounts reflected in the table above, in the future, we may owe royalties and other contingent payments to our collaborators and licensors, based on the achievement of product sales and specified other objectives and milestones, including a minimum annual product purchase commitment to Ethypharm pursuant to the ANTARA license agreement.

**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, 2007 we did not have any financing arrangements that were not reflected in our consolidated balance sheet.

The interest rates on the Note to Paul Capital and our 2009 Notes, Original 2011 Notes and New Notes are fixed and therefore not subject to interest rate risk.

**Item 8. Financial Statements and Supplementary Data**

Financial statements and supplementary data required by Item 8 are set forth at the pages indicated in Item 15(a) below.

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

None.



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**Item 9A. Controls and Procedures**

**Conclusion Regarding The Effectiveness Of Disclosure Controls And Procedures**

We currently have in place systems relating to disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934). Our principal executive officer and principal financial officer evaluated the effectiveness of these disclosure controls and procedures as of the end of our fiscal year ended December 31, 2007 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, 2007 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, 2007.

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**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Shareholders of

Oscient Pharmaceuticals Corporation

We have audited Oscient Pharmaceuticals Corporation's internal control over financial reporting as of December 31, 2007, 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 included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on 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, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, 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, Oscient Pharmaceuticals Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, 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, 2007 and 2006, and the related consolidated statements of operations, shareholders' (deficit) equity, and cash flows for each of the three years in the period ended December 31, 2007 of Oscient Pharmaceuticals Corporation and our report dated February 4, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts

February 4, 2008

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**Item 9B. OTHER INFORMATION**

None.

**PART III**

**Item 10. Directors, Executive Officers and Corporate Governance**

**Executive Officers and Board of Directors**

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 2008 Annual Meeting of Shareholders. Such information is incorporated herein by reference.

**Audit Committee**

Information regarding our Audit Committee and identification of an Audit Committee financial expert may be found under the caption "Board Meetings and Committees - Audit Committee" in the Proxy Statement for our 2008 Annual Meeting of Shareholders. Such information is incorporated herein by reference.

**Section (16A) Beneficial Ownership Reporting Compliance**

Pursuant to General Instruction G(3) to Form 10-K, the 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 2008 Annual Meeting of Shareholders. 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