ABS

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

Form 10-K

FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO SECTIONS 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

(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**

For the transition period from to

Commission file number: 001-33291

Optimer Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**33-0830300**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

10110 Sorrento Valley Road, Suite C, San Diego, California, 92121
(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: **(858) 909-0736**

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

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, par value $0.001 per share	**Nasdaq Global Market**

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 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 the 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, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐	Accelerated filer ☐	Non-accelerated filer ☒ (Do not check if a smaller reporting company)	Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒.

The aggregate market value of the registrant's common stock held by non-affiliates as of June 30, 2007 (without admitting that any person whose shares are not included in such calculation is an affiliate), computed by reference to the price at which the common stock was last sold as of such date on the Nasdaq Global Market, was $154,146,460.

The number of outstanding shares of the registrant's common stock, par value $0.001 per share, as of March 10, 2008 was 27,919,980.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Definitive Proxy Statement for our 2008 Annual Meeting of Stockholders are incorporated by reference in Part III of this report.

OPTIMER PHARMACEUTICALS, INC.

FORM 10-K—ANNUAL REPORT
For the Fiscal Year Ended December 31, 2007
TABLE OF CONTENTS

PART I

Cautionary Note Regarding Forward-Looking Statements

This report and other documents we file with the SEC contain forward looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business or others on our behalf, our beliefs and our management's assumptions. In addition, we, or others on our behalf, may make forward looking statements in press releases or written statements, or in our communications and discussions with investors and analysts in the normal course of business through meetings, webcasts, phone calls and conference calls. Words such as "expect," "anticipate," "will," "could," "would" "project," "intend," "plan," "believe," "predict," "estimate," "should," "may," "potential," "continue," "ongoing", or variations of such words and similar expressions are intended to identify such forward looking statements. These statements are not guarantees of future performance and involve certain risks, uncertainties and assumptions that are difficult to predict. We describe our respective risks, uncertainties and assumptions that could affect the outcome or results of operations in "*Item 1A. Risk Factors*." We have based our forward looking statements on our management's beliefs and assumptions based on information available to our management at the time the statements are made. We caution you that actual outcomes and results may differ materially from what is expressed, implied or forecast by our forward looking statements. Except as required under the federal securities laws and the rules and regulations of the SEC, we do not have any intention or obligation to update publicly any forward looking statements after the distribution of this report, whether as a result of new information, future events, changes in assumptions or otherwise.

Item 1. Business

Overview

We are a biopharmaceutical company focused on discovering, developing and commercializing innovative anti-infective products. Our initial development efforts address products that treat gastrointestinal infections, or GI infections, and related diseases where current therapies have limitations, including diminished efficacy, serious adverse side effects, drug-to-drug interactions, difficult patient compliance and bacterial resistance.

We currently have two late-stage anti-infective product candidates, OPT-80 and Prulifloxacin. OPT-80, our lead product candidate, is an antibiotic currently in two Phase 3 registration trials for the treatment of *Clostridium difficile*-infections, or CDI, also known as *Clostridium difficile*-associated disease, or CDAD, the most common nosocomial diarrhea. Prulifloxacin is an antibiotic currently in two Phase 3 trials for the treatment of infectious diarrhea in travelers, a community-acquired infection which can be caused by a broad range of bacteria. We are developing additional product candidates using our proprietary technology, including our OPopS drug discovery platform.

We were incorporated in November 1998. Since inception, we have focused on developing our product candidates, including OPT-80 and Prulifloxacin.

Antibiotic Market Background

Infectious diseases can be caused by bacteria present in the environment that enter the body through the skin or mucous membranes of the lungs, nasal passages and gastrointestinal tract, or GI tract. These bacteria can be pathogenic, or disease-causing, and can overwhelm the body's immune system by establishing themselves throughout the body in various tissues and organs where they proliferate. This can cause a number of serious and, in some cases, fatal infections, including those of the GI tract, urinary tract, respiratory tract, bloodstream, skin and heart.

Bacteria can be classified as either gram-positive or gram-negative. The difference in classification is largely based on a difference in bacteria cell wall structure in that gram-positive bacteria have exposed thick peptidoglycan, a polymer consisting of sugars and amino acids, cell walls which retain a crystal violet dye during the gram stain process, while gram-negative bacteria do not. Gram-positive bacteria will appear blue or violet under a microscope, whereas gram-negative bacteria will appear red or pink. Antibiotics that treat bacterial infections can be classified as either broad-spectrum or narrow-spectrum. Most antibiotics in use today are generally considered

broad-spectrum, meaning they target a wide variety of bacteria. In contrast, narrow-spectrum antibiotics target a select group of bacteria such as gram-positive or gram-negative bacteria. Current research is increasingly focused on antibiotics that target specific bacteria, which may be beneficial for the treatment of certain infections.

Antibiotics used to treat bacterial infections work by interfering with bacterial cellular activities, such as cell wall synthesis or protein synthesis. Antibiotics may be bacteriostatic or bactericidal. Bacteriostatic antibiotics stop the growth of bacteria, which prevents the infecting bacteria from multiplying and allows the patient's own immune system to eradicate the infecting bacteria. Bactericidal antibiotics work by directly killing the bacteria, which is particularly important for patients with weakened immune systems that cannot effectively eradicate the infecting bacteria on their own.

The anti-infective market is one of the largest therapeutic categories worldwide. According to IMS Health, the combined market for prescription antibacterial drugs in 2006 for the United States, Japan, Korea, Germany, France, Italy, the United Kingdom and Spain exceeded $28.0 billion. The market for anti-infective products is generally divided into two categories, nosocomial infections and community-acquired infections, which represent approximately 30% and 70% of the anti-infectives market, respectively. According to the U.S. Centers for Disease Control and Prevention, or CDC, approximately two million nosocomial infections occur annually in the United States and these infections can increase average length of hospital stays by seven to nine days. Approximately four million nosocomial infections occur annually in Europe, three million in North America, two million in South America and two million in East Asia (excluding China). Nosocomial infections are costly to address, with an estimated annual aggregate healthcare cost in the United States and the United Kingdom of approximately $4.5 billion and $1.9 billion, respectively. In addition, in the United States, nosocomial infections cause approximately 80,000 deaths annually, making them one of the five leading causes of death in the United States. We believe that bacterial infections, especially infections caused by difficult-to-treat, drug resistant bacteria, cause or contribute to a majority of these deaths.

Our Market Opportunity

Many marketed antibiotics used to treat infections have well documented shortcomings. For example, current antibiotics often fail to reach sufficient concentrations at the site of infection to adequately eliminate harmful bacteria. Certain of these antibiotics have also been associated with serious adverse side effects, including renal toxicities, heart rhythm abnormalities, phototoxicity, rashes and central nervous effects, such as seizures. These side effects limit the use of antibiotics for certain patients. In addition, certain antibiotics have interaction issues with prescribed drugs, such as cholesterol lowering agents. Safety problems can arise when increased doses of these antibiotics are needed to treat resistant bacteria. If bacteria develop resistance to currently available antibiotics, the underlying infection can become difficult or impossible to treat, and may even lead to death. Patients also often fail to comply with treatment regimens due to many factors including the inability to tolerate an antibiotic due to its side effects, inconvenient method of dosing and undesirable frequency and length of dosing. Because of these shortcomings associated with marketed antibiotics, we believe an opportunity exists to improve upon existing treatments.

Our Product Candidates

We believe that our product candidates may offer advantages over existing antibiotics in terms of efficacy, safety, potential for minimal bacterial resistance and more convenient dosing. We also believe that the markets for these product candidates present us with significant commercial opportunities. Our product candidates are in various stages of clinical development and none have been approved by the U.S. Food and Drug Administration, or FDA, for sale by us. Our ability to obtain FDA approval of any of our product candidates requires us to successfully complete the clinical development of each such product candidate, including further clinical trials. Clinical trials involve a lengthy and expensive process with an uncertain outcome, and efficacy and safety data of earlier studies and trials may not be predictive of future trial results.

Our current product candidate portfolio consists of the following:

Product Candidate	Target Indications	Development Status	Commercial Rights
Anti-Infectives			
OPT-80 (1)	CDI treatment	Phase 3	Optimer worldwide
	CDI oral suspension	Pre-clinical	
	CDI prevention	Proof-of-concept Trial (2)	
	Prevention of VRE bloodstream infections	Proof-of-concept Trial (2)	
	MRS infections (2nd generation)	Pre-clinical	
Prulifloxacin (OPT-99) (3)	Infectious diarrhea	Phase 3	Optimer U.S.
OPT-1068/CEM-101	Respiratory tract infections	Pre-clinical	Cempra worldwide (4)
Other Therapeutic Areas			
OPT-822/OPT-821 Combination Therapy	Breast cancer	Planning Phase 2	Optimer worldwide
OPT-88	Osteoarthritis	Pre-clinical	Optimer worldwide

(1) We filed an investigational new drug application, or IND, with the FDA for OPT-80 in August 2003.
(2) A proof-of-concept trial is an exploratory clinical trial to provide or establish evidence that a product candidate is efficacious for a target indication.
(3) We filed an IND with the FDA for Prulifloxacin (OPT-99) in December 2005.
(4) We have the right to receive royalties from Cempra Pharmaceuticals, Inc. on any sales of OPT-1068/CEM-101.

Anti-Infective Product Candidates

OPT-80

Overview. We are initially developing OPT-80 for the treatment of infections caused by *Clostridium difficile*, or *C. difficile* bacteria. OPT-80 is a differentiated antibiotic for the treatment of CDI, the most common nosocomial diarrhea. Specifically, OPT-80 has a narrow spectrum of activity against certain gram-positive bacteria. Pre-clinical data indicates that OPT-80 is bactericidal and acts by inhibiting RNA polymerase, a bacterial enzyme. This data also shows that OPT-80 inhibits the growth of other potentially harmful bacteria such as Staphylococci, common bacteria that reside on the skin and in the GI tract, and Enterococci, common bacteria that reside in the GI tract.

OPT-80 is currently in two Phase 3 registration trials for the treatment of CDI. In April 2005, we entered into a collaboration agreement with Par Pharmaceutical, Inc., or Par, pursuant to which we and Par exclusively collaborated in the clinical development and commercialization of OPT-80. In February 2007, we elected to terminate the collaboration agreement with Par, exercised our right under a prospective buy-back agreement to repurchase Par's rights to develop and commercialize OPT-80 in North America and Israel and paid Par a one-time $20.0 million termination fee. As a result, we now hold worldwide rights to OPT-80. The FDA has granted Fast Track status for OPT-80 in the treatment of CDI. Fast Track designation indicates that OPT-80 has the potential to treat life-threatening diseases with unmet medical needs. The FDA also chose OPT-80 to be the only investigational new drug in the FDA's Continuous Marketing Applications, or CMA, Pilot 2 Program in the Division of Anti-Infective and Ophthalmology Products. The CMA designation offers several potential benefits, including a program of continuous FDA feedback designed to streamline the development process. Participation in these programs will not eliminate any phase of clinical development.

Currently, metronidazole and oral vancomycin are the two standard therapeutics used to treat CDI. Both have shortcomings including limited efficacy, high recurrence rates, adverse side effects and poor compliance. Of these two therapeutics, only oral vancomycin is FDA-approved to treat CDI.

Clostridium Difficile-Infections. CDI is a serious illness caused by infection of the inner lining of the colon by *C. difficile*, bacteria that produce toxins resulting in inflammation, severe diarrhea and, in serious cases, death. Outbreaks and illness related to *C. difficile* generally occur during or after therapy with broad-spectrum antibiotics. Broad-spectrum antibiotics can cause CDI by disrupting normally occurring gastrointestinal bacteria, or gut flora, thereby allowing *C. difficile* to proliferate. Recent studies have suggested that the use of proton pump inhibitors, or PPIs, a widely used group of heartburn drugs, may also be linked to *C. difficile* infections. CDI accounts for approximately 20% of antibiotic-associated diarrhea incidences as well as many cases of antibiotic-associated colitis, or inflammation of the colon. C. *difficile* can be transmitted by direct or indirect contact with infected patients via spores that can live for months on dry surfaces. According to the U.S. Centers for Disease Control and Prevention, or CDC, CDI is becoming more prevalent outside the hospital.

We estimate that CDI affected over 500,000 patients in the United States in 2005. In the United Kingdom in 2005, the reported number of CDI patients over 65 years of age was approximately 50,000, and we believe that CDI incidence is growing in patients worldwide. We believe that the incidence of CDI may be higher than what is currently being reported because many hospitals are not required to and do not report incidents of CDI. Additionally, recent reports indicate that the incidence of community-acquired CDI cases may be increasing. For example, a study conducted in one major U.S. city and cited at the 2006 Interscience Conference on Antimicrobial Agents and Chemotherapy, or ICAAC, reported that the percentage of CDI cases found to be community-acquired increased from 12% in 2003 to 22% in 2004 and to 29% in 2005.

According to a study cited in the New England Journal of Medicine, the increased rates of CDI and severity of the disease may be caused by a combination of factors, including the excessive use of antibiotics and the emergence of a new hypervirulent strain of *C. difficile* known as North America Phenotype 1/027, or NAP1/027. A study published in the medical journal Lancet in September 2005 demonstrated that NAP1/027 produces 16 to 23 times more toxins *in vitro* than other strains. NAP1/027 has been reported in over 38 states in the United States and is characterized by increased virulence, morbidity and mortality as well as potential antimicrobial resistance. According to the data presented at the 2006 ICAAC, NAP1/027 incidence in the United Kingdom increased an estimated 200% in the two years after mandatory surveillance of the disease was initiated in hospitals in 2004.

Generally, CDI results in longer hospital stays and increases average patient cost which is often not reimbursed to the hospital. In more complicated cases of CDI, hospitalization may be prolonged by up to two weeks. It has been estimated that each case of CDI in the United States may cost more than $7,000 with total annual expenses to the nation's hospitals estimated at as much as $1.3 billion. According to the data presented at the 2006 ICAAC, CDI results in an estimated increase in average patient cost of over $6,000 per patient in the United Kingdom and the total projected annual cost for treating the disease in Europe is approximately $3.8 billion.

Physicians often care for patients with CDI by discontinuing previously administered broad-spectrum antibiotics, if possible, and providing supportive care such as fluid and electrolyte replacement. If these measures fail, the standard therapy for CDI includes the administration of metronidazole and/or oral vancomycin.

Current Treatments and Limitations. Metronidazole is generally used for patients in the United States and Europe experiencing their first episode or first recurrent episode of CDI. Metronidazole is a generic drug that is used off-label to treat CDI due to its low cost and historical efficacy. The typical treatment regimen for metronidazole is 250 mg every six hours, for a minimum of ten days. Metronidazole can be associated with numerous adverse side effects such as seizures, toxic reactions to alcohol, leukopenia, or reduction of white blood cells, neuropathy, a disease affecting one or more nerves, unpleasant taste or dry mouth.

Oral vancomycin is used in the United States and also in Europe and Japan for the treatment of CDI. As a result of its broad antibacterial activity, intravenously administered vancomycin is frequently used for certain other life-threatening infections caused by multi-drug resistant bacteria. In an effort to slow the continuing emergence of vancomycin-resistant bacteria, the medical community discourages the use of the drug for the treatment of CDI except for patients who are not responding to metronidazole or for patients with severe, life-threatening colitis. Oral vancomycin's recommended treatment protocol is 125 mg or 250 mg doses every six hours, for approximately ten days.

Both metronidazole and oral vancomycin have shortcomings as treatments for CDI including:

- Limited Efficacy. A recent controlled study conducted in North America showed that approximately 19% of CDI patients treated with oral vancomycin and 28% of CDI patients treated with metronidazole do not respond to therapy, and these patients are at risk of developing more severe CDI.

- High Recurrence Rate. Approximately 20% of CDI patients who initially respond to oral vancomycin and 30% of CDI patients who initially respond to metronidazole experience a clinical recurrence following the cessation of antibiotic administration.

- Bacterial Resistance. Widespread use of oral vancomycin is discouraged for the treatment of CDI in some hospitals due to concerns over the development of cross-resistance, including vancomycin-resistant Enterococci, or VRE, and vancomycin-resistant Staphylococcus, which can also cause other serious nosocomial infections. Furthermore, *C. difficile* resistance to metronidazole has been reported in at least one recent study.

- Adverse Side Effects. Metronidazole, which is systemically absorbed and must be administered in high doses to treat CDI, may result in serious adverse side effects and complications, including seizures, toxic reactions to alcohol, leukopenia, neuropathy, unpleasant taste or dry mouth.

- Inducement of CDI. Oral vancomycin and metronidazole are both broad-spectrum antibiotics that disrupt the normal gut flora. Because normal and healthy gut flora generally suppress the growth of *C. difficile*, administration of oral vancomycin or metronidazole may actually induce the development of CDI.

- Inconvenient Dosing and Difficult Compliance. The current treatment regimen for both oral vancomycin and metronidazole is inconvenient as both must be administered every six hours for a minimum of seven days, which may result in lower levels of patient compliance.

Potential OPT-80 Advantages. OPT-80 is a differentiated macrocycle antibiotic consisting of an 18-member ring structure. OPT-80 has significant differentiating features, including a narrow antimicrobial spectrum, fast-acting bactericidal activity against *C. difficile*, minimal systemic exposure and an enduring clinical effect. Based on our clinical and pre-clinical studies of OPT-80 for the treatment of CDI, we believe OPT-80 may offer the following advantages:

- Demonstrated activity against *C. difficile*, including hypervirulent strains such as NAP1/027, with low rates of treatment failures and recurrences;

- Evidence of low *C. difficile* resistance, including hypervirulent strains such as NAP1/027;

- Minimal systemic exposure resulting in a favorable safety profile;

- Limited disruption of normal gut flora resulting in a lower likelihood of inducement of CDI and decreased severity of disease; and

- Convenient, twice daily dosing regimen.

Clinical Development

Phase 3 Pivotal Trials. Based on our Phase 2a clinical trial results, in May 2006, we initiated a North American double blind, randomized, parallel group Phase 2b/3 study to compare the safety and efficacy of OPT-80 dosed at 200 mg twice daily (400 mg/day), versus oral vancomycin dosed at its recommended dosing regimen of 125 mg every six hours (500 mg/day) for ten days, in CDI patients. In the initial Phase 2b portion of the trial, we enrolled a total of 100 CDI patients at 32 sites. Following an interim blinded safety analysis by an independent data safety monitoring board, we transitioned into a Phase 3 clinical trial in March 2007. We expanded the number of

sites to approximately 100 with a target total enrollment of approximately 530 evaluable CDI patients. The primary endpoint for the Phase 3 trial is clinical cure of CDI, as determined by the treating physician for each patient two days after the end of treatment. A secondary endpoint is recurrence, as determined four weeks following treatment. We initiated a second Phase 3 pivotal trial of the same design in the second quarter of 2007. We anticipate enrollment in the first trial will be completed in the next few months and we anticipate completing enrollment and reporting data on the second trial in 2009. If both trials are successful, we intend to file a New Drug Application, or NDA, as soon as practical thereafter.

Phase 2a Study. In July 2005, we completed an open-label, dose-ranging, randomized safety and clinical evaluation study of OPT-80 in patients with CDI at five sites. OPT-80 was administered to 48 patients. Three patients withdrew from the trial for reasons unrelated to the administration of OPT-80, resulting in 45 patients eligible for evaluation. Forty-one of these patients completed a ten-day therapy regimen consisting of twice daily doses of 50 mg (100 mg/day), 100 mg (200 mg/day) or 200 mg (400 mg/day). A primary endpoint of the trial was clinical cure of CDI, as determined by the treating physician for each patient on the tenth day of administration. Additional endpoints investigated were time-to-resolution of diarrhea, recurrence rate through six weeks post-treatment and total relief of CDI symptoms, defined as complete relief of diarrhea, fever and abdominal pain, and normalized white blood cell counts by the end of the ten-day therapy.

Among the 45 evaluated patients, only four patients failed to achieve clinical cure by the end of ten days of therapy, two of whom were in the 100 mg/day dose group and two of whom were in the 200 mg/day dose group. None of the patients in the 400 mg/day dose group failed to achieve clinical cure. All 41 cured subjects were subsequently monitored for six weeks following therapy for recurrence. CDI recurred in two of the 41 cured subjects, one in the 100 mg/day dose group and one in the 400 mg/day dose group. The median cure times, or time-to-resolution of diarrhea, were as follows: 5.5 days for the 100 mg/day dose group, 3.5 days for the 200 mg/day dose group and 3.0 days for the 400 mg/day dose group.

A summary of the results of the Phase 2a clinical trial for OPT-80 is presented below:

	Dose Group		
Parameter	**100 mg/day**	**200 mg/day**	**400 mg/day**
Clinical Cures	86% (12/14)	87% (13/15)	100% (16/16)
Total Symptom Relief	43% (6/14)	53% (8/15)	81% (13/16)
Recurrence	8% (1/12)	0% (0/13)	6% (1/16)
Median Time to Cure of Diarrhea	5.5 Days	3.5 Days	3.0 Days

Pharmacokinetic analyses were performed on all patients. OPT-80 was not detectable in the blood in half of the patients and only three subjects had levels exceeding 0.02 mg/mL. Stool concentrations of OPT-80 averaged over 1,400 mg/g of stool at the 400 mg/day dose level at day ten. As *C. difficile* is present mainly in the gut, high stool concentrations suggest that OPT-80 is present where needed to treat CDI and low concentrations in the blood indicate OPT-80 is minimally absorbed in the system, thus reducing the risk of side effects. There were no adverse events determined by the physicians to be related to OPT-80. At one site in this Phase 2a trial, we performed a microbiologic analysis of the stool of 29 patients. This analysis showed that OPT-80 did not cause any unusual disruptions of normal gut flora for patients in any of the three dose groups.

Phase 1 Studies. We have completed two double-blind, oral, dose-escalating, placebo-controlled Phase 1 trials, one of which was a Phase 1a single-dose trial, and one of which was a Phase 1b multiple-dose trial. The trials were designed to determine the safety, tolerability, and pharmacokinetic characteristics of OPT-80 in healthy volunteers. Each Phase 1a patient received two single oral administrations of either a 100 mg dose followed by a 300 mg dose, or a 200 mg dose followed by a 450 mg dose of OPT-80. Each Phase 1b patient received daily oral administrations of 150, 300, or 450 mg doses of OPT-80 for ten consecutive days. In both trials, there were eight subjects for each dose level, six of whom were randomly selected to receive OPT-80 and two of whom received placebo. We collected blood, urine and stool samples for pharmacokinetic analysis. Vital signs including blood pressure, pulse, body temperature and electrocardiograms were measured following each dosing and on a regular basis throughout the study. In both studies, OPT-80 was well tolerated by all subjects and no drug-related adverse events were observed.

OPT-80 also exhibited a favorable pharmacokinetic profile for CDI treatment. After oral administration at either single dose or multiple doses, all blood samples had low, usually lower than 0.02 mg/mL, or undetectable levels of OPT-80 which indicates very low systemic absorption. In contrast, OPT-80 was found to be present in high concentrations in the stool. For example, at day ten for the 450 mg per day multiple-dose group, the mean OPT-80 stool concentration exceeded 10,000 times the MIC_{90}, or minimum concentration of a drug needed to inhibit growth of 90% of microorganisms, of *C. difficile*.

Oral Suspension Formulation Development. We are developing an oral suspension formulation which complements the existing tablet form of OPT-80. This formulation is intended for use with intensive care unit and elderly patients. We plan to file an IND for potential label expansion.

Commercialization

In April 2005, we entered into a collaboration agreement with Par pursuant to which we and Par exclusively collaborated to develop and commercialize OPT-80. We had granted to Par an exclusive royalty-bearing license, with the right to sublicense, promote, market, distribute and sell OPT-80 in a territory composed of the United States, Canada and Puerto Rico, with an option to extend the territory to include Israel. We retained all other rights to OPT-80 in the rest of the world. In January 2007, we entered into a prospective buy-back agreement with Par which provided us with an option to terminate the collaboration and repurchase the rights to develop and commercialize OPT-80 in North America and Israel.

In February 2007, we elected to terminate the collaboration agreement pursuant to the prospective buy-back agreement with Par and we have repurchased the rights to develop and commercialize OPT-80 in North America and Israel. We now hold worldwide rights to OPT-80. Under the terms of the prospective buy-back agreement, we paid Par a one-time $20.0 million termination fee and purchased $1.9 million of OPT-80 clinical supply material and active pharmaceutical ingredient from Par. We are also obligated to pay Par a one-time $5.0 million milestone payment, a 5% royalty on net sales by us or our affiliates of OPT-80 in North America and Israel, and a 1.5% royalty on net sales by us or our affiliates of OPT-80 in the rest of the world. In addition, in the event we license our right to market OPT-80 in the rest of the world, we will be required to pay Par a 6.25% royalty on net revenues we receive related to OPT-80. We are obligated to pay each of these royalties, if any, on a country-by-country basis for seven years commencing on the applicable commercial launch in each such country.

OPT-80 — Other Indications

Based on our pre-clinical and clinical studies for CDI treatment, we believe OPT-80 may be effective against a broad range of indications with significant unmet medical needs. Our strategy is to develop OPT-80 for its lead indication, CDI treatment, while also advancing its development for additional indications.

CDI Prevention. We believe OPT-80 may be effective not only for treating CDI but also for preventing CDI. Patients at high risk of developing CDI, such as elderly patients in long-term care facilities or hospital patients on broad-spectrum antibiotics or PPIs, may benefit from prophylactic protection from the disease. Up to 20% of long-term care patients are colonized with *C. difficile*. There is currently no therapeutic drug approved for the prevention of CDI. Incidence of CDI outbreaks has been increasing in the hospital and community settings, and we believe OPT-80 may provide safe, potent and narrow-spectrum bactericidal activity against *C. difficile*, thereby protecting high-risk patients while limiting disruption to normal gut flora. We continue to evaluate the design of a proof-of-concept clinical trial of OPT-80 to prevent CDI disease in high-risk populations.

Prevention of Nosocomial VRE Bloodstream Infections. Pre-clinical data indicate that OPT-80 is active *in vitro* against antibiotic-resistant Enterococci, including VRE. Enterococci are common bacteria that reside in the GI tract and generally do not pose a serious health risk. However, if Enterococci enter the bloodstream, they can cause serious and life-threatening infections, especially in subjects with weakened immune systems. Vancomycin is considered the last line of defense against such infection. However, growing bacterial resistance to vancomycin has emerged, requiring new therapeutic options.

Biological and stool concentration data from our Phase 1 and 2a CDI treatment trials indicate OPT-80 may be useful in the prevention of VRE bloodstream infections by minimizing the colonization of these bacteria in the GI

tract before they enter into the bloodstream. We are planning to conduct a proof-of-concept clinical trial for this additional indication.

Methicillin-Resistant Staphylococci, or MRS, Infections. We believe second generation OPT-80 compounds may be useful for the treatment of Staphylococcal infections. Methicillin is a broad-spectrum antibiotic that was previously used to treat infections caused by susceptible gram-positive bacteria, such as *Staphylococcus aureus*, or *S. aureus*, and *Staphylococcus epidermidis*, or *S. epidermidis*, that would otherwise be resistant to most penicillins.

Prulifloxacin (OPT-99)

Overview. We are developing Prulifloxacin for the treatment of infectious diarrhea, including travelers' diarrhea, a community-acquired infection which can be caused by a broad range of bacteria. We intend to seek a label for Prulifloxacin for the treatment of infectious diarrhea in travelers and initially plan to focus commercialization efforts on the treatment of travelers' diarrhea. Prulifloxacin is a prodrug in the fluoroquinolone class of antibiotics, a widely-used class of broad-spectrum antibiotics. A prodrug is an inactive form of a compound that is converted in the body to an active drug either by spontaneous chemical reaction or through the enzymatic process. Following oral administration, Prulifloxacin is converted to ulifloxacin, which is rapidly bactericidal by killing susceptible bacterial pathogens through inhibition of DNA replication. Ulifloxacin has demonstrated potent broad-spectrum activity against gram-positive and gram-negative bacteria. We are currently conducting two Phase 3 clinical trials of Prulifloxacin for the treatment of travelers' diarrhea. We believe that Prulifloxacin will be a differentiated therapeutic option for travelers' diarrhea due to its broad and potent activity against gastrointestinal pathogens, favorable safety profile, clinical efficacy and convenient dosing regimen.

In June 2004, we acquired from Nippon Shinyaku Co., Ltd., the exclusive rights to develop and commercialize Prulifloxacin for all indications in the United States. Prulifloxacin has been marketed by other companies in Japan since 2002 to treat a wide range of bacterial infections, including infectious diarrhea, and in Italy since 2004 to treat urinary tract infections, or UTIs, and respiratory tract infections, or RTIs. Other parties have established that Prulifloxacin is well-tolerated, as demonstrated by its use in the treatment of more than two million patients. A 1996 investigator-initiated clinical study of Prulifloxacin in Japan by a third party for the treatment of infectious diarrhea evaluated the safety and efficacy of Prulifloxacin in 122 subjects, with an endpoint of clinical cure, as evidenced by eradication of bacterial pathogens. Prulifloxacin was considered effective in approximately 98% of the 54 subjects evaluated for clinical cure. Prulifloxacin also eradicated the bacterial pathogen in approximately 95% of the 77 subjects evaluated for bacteriological effect. One hundred eight of the 109 subjects evaluated for safety had no adverse effects while one subject experienced a mild rash that was possibly related to Prulifloxacin administration, but quickly recovered and continued to receive all scheduled therapy.

Infectious Diarrhea. Infectious diarrhea is associated with an infection caused by bacteria, viruses or parasites. Its symptoms include stomach cramps, vomiting, nausea, fever and headache. Infectious diarrhea is the world's second-leading cause of morbidity and mortality. It is a significant problem even in the United States where it is often found in otherwise healthy individuals.

Travelers' diarrhea is infectious diarrhea contracted by the ingestion of contaminated food or water. The CDC estimates that there are approximately 50,000 cases of travelers' diarrhea each day among the 50 million worldwide annual travelers to developing countries. We estimate that approximately 23 million patients are treated with antibiotics for infectious diarrhea annually in the United States. Bacteria cause approximately 85% of travelers' diarrhea in most localities, and the majority of these cases involve *E. coli*, Shigella or Salmonella. Severe infections can cause large fluid loss and result in dehydration and hospitalization. The CDC estimates that 30% to 50% of travelers to high-risk regions (including most of Asia, the Middle East, Africa, Central America and South America) will develop travelers' diarrhea during a one- to two-week visit. The risk of infection increases with the duration of travel, and infection is possible throughout the world. A study of Americans visiting developing countries found that 46% acquired diarrhea.

Current Treatments and Limitations. Authorities such as the Infectious Disease Society of America and the CDC recommend treatment for travelers' diarrhea with an antibiotic that has an appropriate spectrum of activity against typical pathogens related to travelers' diarrhea. These antibiotics include fluoroquinolones such as ciprofloxacin, macrolides such as azithromycin, sulfonamides such as trimethoprim-sulfamethoxazole, or

TMP/SMX, tetracyclines such as doxycycline, and rifamycins such as rifaximin. Fluoroquinolones remain the first-line treatment for infectious diarrhea because of their bactericidal nature, broad spectrum of activity and generally well-tolerated profile.

Many of the treatments for travelers' diarrhea have significant limitations. Limitations of ciprofloxacin, rifaximin and TMP/SMX, three of the most commonly prescribed treatments for infectious diarrhea, include one or more of the following:

- Limited Spectrum of Activity and Antimicrobial Resistance. Rifaximin is approved only for the treatment of travelers' diarrhea caused by noninvasive strains of *E. coli*. Rifaximin is not recommended for the treatment of diarrhea caused by other pathogens commonly associated with travelers' diarrhea such as Shigella, Salmonella, Aeromonas, Campylobacter, Plesiomonas, and Yersinia. In addition, our studies with a panel of 582 infectious diarrhea-associated bacteria have shown that 25% of *E. coli* and 67% of Shigella strains associated with travelers' diarrhea are resistant to TMP/SMX.

- Possible Side Effects. Ciprofloxacin has been associated with phototoxicity and QT interval prolongation, a condition that is associated with potentially life-threatening cardiac arrhythmias. Rifaximin has been linked to allergic reactions to the drug. TMP/SMX has been associated with both frequent mild allergic reactions and rare but serious adverse effects including bone marrow suppression, severe liver damage, severe renal impairment and agranulocytosis, an acute condition related to leukopenia.

- Convenience and Compliance. Ciprofloxacin is approved as therapy for infectious diarrhea with a dosing regimen of twice daily administrations for five to seven days. Rifaximin is approved as a therapy for diarrhea caused by noninvasive *E. coli* and is typically given three times daily for three days. These treatment regimens may be inconvenient for traveling patients.

Prulifloxacin Advantages. We believe that Prulifloxacin will be a differentiated and a better therapeutic course for bacterial infectious diarrhea for several reasons, including:

- Efficacy. Prulifloxacin has been established to be an effective therapy for infectious diarrhea in clinical studies by third parties in Japan. Ulifloxacin, the active metabolite of Prulifloxacin, quickly reached effective concentration levels following a single administration of the drug in patients with profuse diarrhea. Approximately two-thirds of the oral dose of Prulifloxacin remains in the stool after being converted to ulifloxacin while approximately one-third is absorbed and accumulated in tissues and in phagocytes, the white blood cells which engulf bacterial pathogens. Ulifloxacin remains active in these tissues and available in the body to eliminate invasive and intracellular pathogens such as Shigella and Salmonella and invasive forms of *E. coli*.

- Spectrum of Activity. Ulifloxacin has more potent antibacterial activity relative to other antibacterial agents against infectious diarrhea pathogens. In a pre-clinical study we commissioned, ulifloxacin was the most active of nine antibacterial agents tested against a panel of 582 international infectious diarrhea-associated bacteria. The potency of six of these agents against common bacterial pathogens that cause diarrhea is shown below, normalized to the potency of rifaximin:

	Comparative Potency Against Bacteria(1)		
Antibacterial	E. coli (100 isolates)	Salmonella (101 isolates)	Shigella (101 isolates)
Ulifloxacin	2,000	533	2,000
Ciprofloxacin	1,000	133	1,000
Azithromycin	4	4	4
Rifaximin	1	1	1
Doxycycline	1	0.5	0.5
TMP/SMX	≤0.25	≥32	≤0.25

(1) The potency of an antibiotic normalized to rifaximin is expressed as the quotient obtained by dividing the MIC_{90} concentration of rifaximin by the MIC_{90} concentration of that antibiotic.

- Side Effects. Prulifloxacin has an established and favorable safety profile with minimal potential to produce adverse side effects associated with other treatments for travelers' diarrhea, such as QT interval prolongation, phototoxicity, or central nervous system effects.

- Convenience and Compliance. If approved, we expect Prulifloxacin will be marketed as therapy for infectious diarrhea with a convenient dosing regimen of one tablet daily for three days.

On-Going Clinical Development and Next Steps. We are currently conducting two Phase 3 clinical trials for the registration of Prulifloxacin in the United States for the treatment of bacterial infectious diarrhea.

- *Phase 3 Trials.* The first trial, being conducted in the United States, Mexico and Peru, was initiated in July 2006 and is a randomized, double-blind placebo-controlled clinical trial in which two-thirds of the patients will receive Prulifloxacin in 600 mg doses and one-third of the patients will receive a placebo. We initiated the second trial in December 2006 in India, and subsequently added additional sites in other countries. This second trial is also a randomized, double-blind placebo-controlled clinical trial in which half of the patients will receive Prulifloxacin in 600 mg doses and half of the patients will receive placebo. The primary endpoint of both trials is time to last unformed stool. Secondary endpoints include microbiological eradication of the disease pathogen and relief of other disease symptoms. We have completed enrollment in the first trial and expect data in the next few months. We currently anticipate completing enrollment and reporting data in the second trial during the second half of 2008, and assuming positive results, filing an NDA as soon as practical thereafter.

- *Proposed Phase 4 Marketing Support Trial.* We anticipate that this trial will be a randomized, double-blind clinical trial using ciprofloxacin as a comparator. We plan to initiate this trial subsequent to NDA submission of Prulifloxacin.

Additional Indication for Urinary Tract Infection. After the anticipated launch of Prulifloxacin for the treatment of infectious diarrhea, we may seek additional approval of Prulifloxacin for the treatment of complicated UTIs, which are commonly caused by bacteria such as *E. coli*, Staphylococcus saprophyticus and Pseudomonas aeruginosa. According to the Kidney and Urology Foundation of America, an estimated ten million physician office visits in 2002 were due to UTIs, the second leading cause of infection following RTIs. UTIs account for up to 40% of nosocomial infections and, when present, can increase the average hospital patient cost by approximately $675 per patient. According to IMS Health, global sales of UTI prescription antibiotics exceeded $1.1 billion in 2003, with the United States accounting for approximately 62% of this market. We believe Prulifloxacin's advantages as a therapy for infectious diarrhea can be leveraged in the approval for treatment of complicated UTIs. Prulifloxacin is currently approved as therapy for complicated and uncomplicated UTIs in Italy and Japan. Prulifloxacin was compared to ciprofloxacin as therapy for complicated lower UTIs in a 257-patient, double-blind, comparator-

controlled clinical trial that was conducted in Europe by third parties. In patients that were administered Prulifloxacin once daily for 10 days, clinical resolution of the infection was achieved in approximately 95% of patients and the pathogen was eradicated in approximately 90% of patients. In contrast, in patients that were administered ciprofloxacin twice daily for 10 days, clinical resolution was achieved in approximately 93% of patients and the pathogen was eradicated in approximately 78% of patients. A similar open-label study produced microbiological eradication and clinical cure in approximately 93% and approximately 96%, respectively, of 113 Prulifloxacin-treated patients.

Our OPopS Drug Discovery Platform

Background. Carbohydrates are the most abundant class of biological molecules in nature and are fundamental to many physiological processes, which can be inhibited or augmented by carbohydrate-based drugs. We believe these processes represent potential drug targets for infectious diseases, cancer and immune-related disorders. Carbohydrates, however, can be difficult to synthesize because of their complex molecular structure. Historically, the synthesis of complex carbohydrate molecules took weeks to months to complete, and thus carbohydrate synthesis for use in therapeutics has often been characterized as prohibitively difficult and time-consuming. Numerous drugs currently on the market have carbohydrate components, which are often implicated in bacterial resistance, and numerous diseases involve interactions with carbohydrate molecules. Carbohydrate synthesis involves the manipulation of existing drugs to improve their spectrum of activity or significantly reduce their side effects. Such drugs include aminoglycosides, glycopeptides, macrolides and antivirals.

Our Technology. Our proprietary OPopS drug discovery platform allows us to develop potential drug candidates through carbohydrate drug synthesis. OPopS is a computer-aided technology that enables the rapid and low cost synthesis of a wide array of carbohydrate-based compounds. Specifically, the two components of our OPopS technology that allow us to synthesize new compounds are:

- *GlycoOptimization.* This process enables the modification of a carbohydrate group on an existing drug to improve its properties.

- *De Novo Glycosylation.* This process enables the addition of new carbohydrate groups on an existing drug to create new, patentable compounds.

We acquired worldwide rights to this technology from The Scripps Research Institute, or TSRI, in July 1999. We have built approximately 500 carbohydrate building blocks, and through our proprietary OptiMer software program, we are able to rapidly and reliably produce a wide variety of carbohydrate-based molecules. With OPopS, we are able to reduce the time required for the synthesis of these molecules from weeks or months to hours. We believe OPopS enables us to develop patentable drugs, optimizing drug performance, improving activity, overcoming bacterial resistance issues and/or improving side effect profiles. Several of our pre-clinical drug candidates have been developed with OPopS and we intend to use this technology to identify additional novel carbohydrate-based product candidates with significant commercial potential.

Other Pipeline Product Candidates

Using our OPopS technology, we are developing a pipeline of promising new drug candidates for the treatment of various indications including infectious disease, osteoarthritis and breast cancer. Our strategy is to license these drug candidates opportunistically to third-party partners in order to maximize the potential for their development and commercialization. The most advanced pipeline product candidates are as follows:

OPT-88: A Therapy for Osteoarthritis

Overview. We intend to develop our carbohydrate-based product candidate OPT-88 as a disease-modifying intra-articular, or within the cavity of a joint, therapy for osteoarthritis. Osteoarthritis is caused by the breakdown and eventual loss of the cartilage of one or more joints in the body. Key symptoms include pain in joints such as knees, hips and fingers, inability to walk or bear weight and infection surrounding such joints. There are no currently marketed treatments for the underlying disease. According to the National Institute of Arthritis and Musculoskeletal and Skin Diseases, osteoarthritis is one of the most common types of joint diseases and is estimated to affect 33

million people in the United States in 2006. Pre-clinical studies of OPT-88 indicate reduced erosion of knee cartilage and a reduction of pain for up to nine days after a single injection. With its disease-modifying activity and tolerability profile, OPT-88 represents a potentially new intra-articular therapy, and we believe it is a significant product opportunity for the osteoarthritis market.

Pre-Clinical Studies and Future Plans. In vitro studies of OPT-88 in human cell cultures have shown that it significantly stimulates restoration of joint cartilage. Animal studies demonstrated a reduced pathology and reduction in the erosion of knee cartilage. We held a pre-Investigational New Drug application, or pre-IND, meeting with the FDA in the first quarter of 2008 and plan to file an IND application for OPT-88 in the second half of 2008 to initiate a Phase 1 study for assessing the safety of repetitive intra-articular injections in patients with knee osteoarthritis using an escalating dose scheme. If the Phase 1 study is successful, we plan to conduct a subsequent proof-of-concept Phase 2 efficacy study. After our Phase 2 study, we would likely seek a partner to fully develop and commercialize OPT-88.

OPT-822/OPT-821: A Cancer Immunotherapy

Overview. We are currently developing our carbohydrate-based product candidate OPT-822 combined with OPT-822's adjuvant therapy OPT-821, a carbohydrate-based immunostimulant therapy, for the treatment of metastatic breast cancer. According to the American Cancer Society, breast cancer was the second most common form of cancer among women in the United States, with more than 200,000 new cases and 40,000 deaths estimated in 2005. The survival rate for patients with metastatic breast cancer remains limited, with a median survival of two to three years and a five-year survival rate of less than 20% for those patients diagnosed with late-stage cancer that has metastasized to other parts of the body. In July 2002, we acquired exclusive rights from Sloan-Kettering Institute for Cancer Research, or SKI, to develop and commercialize OPT-822 worldwide. Carbohydrate antigens are known to stimulate the immune response against cancer cells in the body. We have applied OPopS technology to manufacture effectively complex carbohydrate cancer antigens, including Globo-H, a prominent antigen in breast cancer cells, and sialyl Lewis a, an antigen in breast and small lung cancer cells. OPT-822 is a novel cancer immunotherapy and is composed of Globo H linked to a protein carrier.

Clinical Studies and Future Plans. SKI completed Phase 1 safety studies of OPT-822 in prostate cancer patients and breast cancer patients in 1999 and 2001, respectively. In these studies, OPT-822 appeared to be well tolerated and to stimulate response to tumor antigens. Eighteen of 27 metastatic breast cancer patients treated with OPT-822 in the studies survived after five years. We also plan to evaluate the clinical efficacy of OPT-822 combined with OPT-822's adjuvant therapy OPT-821. We currently plan to identify a strategic partner, apply for government grants for subsequent clinical trials, and then initiate a Phase 2/3 clinical trial in Asia.

OPT-1068/CEM-101: Macrolide and Ketolide Antibiotics

Macrolide antibiotics have been marketed for the treatment of upper and lower respiratory tract infections. Macrolides such as erythromycin and azithromycin, and ketolides, such as telithromycin, are related classes of antibiotics which have strong gram-positive activity and inhibit bacterial growth. However, an increasing number of pathogens are now resistant to currently available macrolides and ketolide. Two of our leading product candidates developed with our discovery technology, including glycooptimization, OPT-1068/CEM-101, are effective against these resistant bacterial strains. These product candidates have been shown to possess potent activity against multi-drug resistant Streptococcus pneumoniae and Streptococcus pyogenes, common RTI pathogens. OPT-1068, the most advanced lead candidate, is orally active with potent efficacy in animal models after once-a-day administration. Cempra has licensed from us a library of approximately 500 macrolides related to these two product candidates. Cempra has informed us that it is initially planning to develop OPT-1068 for RTIs in adults and children, including sinusitis, an infection of the sinus, pharyngitis, an infection of the pharynx, and community-acquired mild and moderate pneumonia.

Our Strategy

Our principal objective is to become a leading biopharmaceutical company focused on the discovery, development and commercialization of innovative anti-infective compounds, with an initial focus on gastrointestinal infections and related diseases. To achieve these objectives, our strategy includes the following key elements:

- *Build a branded anti-infective franchise through current and in-licensed product candidates.* We currently have two late-stage antibiotic product candidates, OPT-80 for the treatment of CDI, and Prulifloxacin for the treatment of infectious diarrhea in travelers. We also intend to develop these two lead products for additional indications and selectively in-license additional anti-infective compounds for development and/or commercialization. In addition, in order to maximize the value of our franchise, we intend to opportunistically seek partners to commercialize our product candidates outside of our core markets. We believe our management's industry knowledge and contacts will be a significant advantage in executing this part of our strategy.

- *Develop our lead product candidates for clinical and regulatory approval.* We are currently focusing our resources on developing OPT-80 and Prulifloxacin. OPT-80 potentially offers significant advantages over existing therapeutics for CDI, a serious and growing hospital-acquired illness. Prulifloxacin also potentially offers significant advantages over existing therapeutics for infectious diarrhea and has an extensive record of safety and efficacy, having been used in over two million patients in Europe and Japan. If our trials for OPT-80 for the treatment of CDI are successful, we plan to file an NDA for OPT-80 as soon as practical thereafter. If our trials for Prulifloxacin for the treatment of travelers' diarrhea are successful, we plan to file an NDA for Prulifloxacin as soon as practical thereafter.

- *Build marketing and sales capabilities in our core markets.* Our objective is to market innovative antibiotics in areas of unmet medical needs for the treatment and prevention of nosocomial and serious community-acquired infections. Specifically, we initially plan to commercialize and develop OPT-80 and Prulifloxacin in key defined markets. In order to achieve these goals, we intend to develop our own marketing organization and sales force, as well as evaluate partnering alternatives to commercialize our product candidates.

- *Leverage our internal discovery capabilities and expertise in carbohydrate chemistry to expand our portfolio of product candidates.* We intend to expand our product portfolio by exploiting our internal expertise to discover and develop additional product candidates. We believe our proprietary technology and our capabilities and expertise in carbohydrate chemistry will enable us to more rapidly identify and develop successful product candidates. We may opportunistically seek partners for the development and commercialization of product candidates in order to maximize value and maintain our strategic focus.

Marketing and Sales

We currently have no marketing, sales or distribution capabilities. However, we plan to develop these capabilities internally or through collaborations with third parties. In February 2007, we elected to terminate our collaboration agreement with Par and exercised our right to repurchase Par's rights to develop and commercialize OPT-80 in the North America and Israel. We now hold worldwide rights to OPT-80. We plan to build our own marketing and sales force for OPT-80 in North America and Prulifloxacin in the United States. We plan to seek collaborations with one or more third parties for the commercialization of OPT-80 outside of North America. We plan to target our marketing and sales of OPT-80 to hospital-based and long-term care physicians, including gastroenterologists, infectious disease specialists and internists. If OPT-80 and Prulifloxacin are approved by the FDA, we intend to develop a marketing and sales force in the United States to commercialize both OPT-80 and Prulifloxacin in this market. We plan to target our marketing and sales of Prulifloxacin to high-prescribing physicians of antibiotics for travelers' diarrhea, including those at travel clinics.

We continue to evaluate the marketing and sales capabilities that will be necessary to launch and commercialize OPT-80 and Prulifloxacin. We are currently building a marketing department and establishing a medical affairs group to introduce our product candidates to key opinion leaders in CDI and healthcare professionals focusing on infectious diseases and gastroenterology.

Collaborations, Commercial and License Agreements and Grants

Par Pharmaceutical, Inc. In January 2007, we entered into a prospective buy-back agreement with Par which provided us with an option to terminate a collaboration agreement entered in April 2005. The collaboration agreement provided that Par would develop and commercialize OPT-80 and granted Par an exclusive royalty bearing license, with the right to sublicense, promote, market, distribute and sell OPT-80 in a territory composed of the United States, Canada and Puerto Rico, with an option to extend the territory to include Israel. We retained all other rights to OPT-80 in the rest of the world (i.e. outside North America).

In February 2007, we elected to terminate the collaboration agreement pursuant to the prospective buy-back agreement with Par and we have repurchased the rights to develop and commercialize OPT-80 in North America and Israel. We now hold worldwide rights to OPT-80. Under the terms of the prospective buy-back agreement, we paid Par a one-time $20.0 million termination fee and $1.9 million for OPT-80 clinical supply material and active pharmaceutical ingredient in 2007. We are also obligated to pay Par a one-time $5.0 million milestone payment, a 5% royalty on net sales by us or our affiliates of OPT-80 in North America and Israel, and a 1.5% royalty on net sales by us or our affiliates of OPT-80 in the rest of the world. The one-time $5.0 million milestone payment shall be paid after the earliest to occur of (i) the successful completion by us of our pivotal Phase 3 trial for OPT-80, (ii) our grant to a third party of the rights to OPT-80 or (iii) the submission to the FDA of an NDA for OPT-80. In the event we license our right to market OPT-80 in the rest of the world, we will be required to pay Par a 6.25% royalty on net revenues we receive related to OPT-80. We are obligated to pay each of these royalties, if any, on a country-by-country basis for seven years commencing on the applicable commercial launch in each such country. The agreement also includes a mutual release between the parties and our indemnification of Par for actions related to OPT-80, the agreements assigned to us by Par and certain other matters.

Biocon. In connection with the exercise of our rights under the prospective buy-back agreement, Par assigned to us a supply agreement with Biocon Limited, or Biocon, regarding the active pharmaceutical ingredient, or API, for OPT-80. Under this agreement, Biocon is obligated to supply to us our requirements of the OPT-80 API for certain markets. The supply agreement will terminate upon the tenth anniversary of the commercial launch of OPT-80 unless earlier terminated by mutual agreement or material default of either party.

Nippon Shinyaku. In June 2004, we entered into a license agreement with Nippon Shinyaku. Under the terms of the agreement, we acquired the non-exclusive right to import and purchase Prulifloxacin, and the exclusive right (with the right to sublicense) within the United States to develop, make, use, offer to sell, sell and license products suitable for consumption by humans containing Prulifloxacin. Additionally, we acquired rights within the United States to a key patent which covers the compound and its use in the treatment of bacterial infections in humans and animals. The key patent will expire in February 2009; however, upon receiving final marketing approval of Prulifloxacin, we plan to apply to extend the term of this key patent for up to an additional five years, under the Drug Price Competition and Patent Term Restoration Act, informally known as the Hatch-Waxman Act. Under the agreement, we also acquired rights to a pending U.S. patent application filed by Nippon Shinyaku in October 2005 which relates to production of a form of Prulifloxacin. If issued, the U.S. pending patent application for Prulifloxacin would expire in 2023.

Under the terms of the agreement, we paid Nippon Shinyaku a $1.0 million upfront licensing fee and will be required to pay Nippon Shinyaku a milestone payment in the amount of $1.0 million upon the filing, if any, of the NDA for Prulifloxacin in the United States. We also agreed to exclusively purchase Prulifloxacin from Nippon Shinyaku and to purchase a certain amount of Prulifloxacin annually that is to be mutually agreed upon by us and Nippon Shinyaku, commencing in the year of the first commercial sale of Prulifloxacin in the United States. If Nippon Shinyaku is unable to supply us with the required amount of Prulifloxacin, then Nippon Shinyaku will grant us a non-exclusive, worldwide license to make or have made Prulifloxacin, in which event we will owe Nippon Shinyaku a royalty based on the amount of net sales of Prulifloxacin generated by us and our sublicensees. Additionally, we will owe Nippon Shinyaku certain royalties based on the amount of net sales of Prulifloxacin less the amount of Prulifloxacin we buy from Nippon Shinyaku.

Either party may terminate the agreement 60 days after giving notice of a material breach which remains uncured 60 days after written notice. If not terminated earlier, the agreement will terminate upon the longer of ten

years from the date of the first commercial sale of Prulifloxacin in the United States or until the date on which the last valid patent claim relating to Prulifloxacin expires in the United States.

Sloan-Kettering Institute for Cancer Research. In July 2002, we entered into a license agreement with Sloan-Kettering Institute for Cancer Research, or SKI, to acquire, together with certain non-exclusive licenses, exclusive, worldwide licensing and sublicensing rights to certain patented and patent-pending carbohydrate-based cancer immunotherapies. As partial consideration for the licensing rights, we paid to SKI a one-time fee consisting of both cash and 55,383 shares of our common stock. Under the agreement, which was amended in June 2005, we owe SKI milestone payments in the following amounts for each licensed product: (i) $500,000 upon the commencement of Phase 3 clinical studies, (ii) $750,000 upon the filing of the first NDA, (iii) $1.5 million upon marketing approval in the United States and (iv) $1.0 million upon marketing approval in each and any of Japan and certain European countries, but only to the extent that we, and not a sublicensee, achieve such milestones. We also owe SKI royalties based on net sales generated from the licensed products and income we source from our sublicensing activities, which royalty payments are credited against a minimum annual royalty payment we owe to SKI during the term of the agreement.

The term of the agreement continues until the later of July 31, 2017, or the expiration of the last to expire of the patents licensed under this agreement, unless the agreement is earlier terminated. The agreement can be terminated by SKI for a variety of reasons, including (i) upon 60 days' notice in the event we fail to meet a development milestone specified in the agreement or (ii) upon 30 days' notice, in the event we fail to pay any licensing fees, royalties or patent expenses due under the agreement within 30 days of the due date and thereafter fail to pay such deficit in-full within the 30-day notice period.

Cempra Pharmaceuticals, Inc. In March 2006, we entered into a collaborative research and development and license agreement with Cempra, a biotechnology company focused on anti-infectives. We are collaborating with Cempra to discover, develop and commercialize drugs based on macrolide and ketolide compounds. We granted to Cempra an exclusive worldwide license, except in Association of Southeast Asian Nations, or ASEAN, countries as of the effective date of the agreement, with the right to sublicense, our patent and know-how related to our macrolide and ketolide antibacterial program, several other pre-clinical compounds and our related proprietary technology. Cempra is responsible for many of the costs associated with the development and commercialization of product candidates arising under agreement, including manufacturing, marketing and sales costs. As partial consideration for granting Cempra the licenses, we obtained common stock of Cempra. We will receive milestone payments as product candidates are developed and/or co-developed by Cempra. The milestone payments will be triggered upon the completion of certain clinical development milestones and in certain instances, regulatory approval of products. The aggregate amount of such milestone payments we may receive is based in part on the number of products developed under the agreement and can exceed $24.5 million. We will also receive royalty payments based on a percentage of net sales of licensed products. In consideration of the foregoing, Cempra will receive milestone payments of $1.0 million from us for each of the first two products we develop which receive regulatory approval in ASEAN countries as well as royalty payments on the net sales of such products.

The research term of this agreement will be completed on March 31, 2008. Subject to certain exceptions, on a country-by-country basis, the general terms of this agreement continue until the later of: (i) the expiration of the last to expire patent rights of a covered product in the applicable country or (ii) ten years from the first commercial sale of a covered product in the applicable country. Either party may terminate the agreement in the event of a material breach by the other party, subject to prior notice and the opportunity to cure. Either party may also terminate the agreement for any reason upon 30 days' prior written notice provided that all licenses granted by the terminating party to the non-terminating party shall survive upon the express election of the non-terminating party.

The Scripps Research Institute. In July 1999, we acquired exclusive, worldwide rights to OPopS technology from The Scripps Research Institute, or TSRI. This agreement includes the license to us of patents, patent applications and copyrights related to OPopS technology. We also acquired, pursuant to three separate license agreements with TSRI, exclusive, worldwide rights to over 20 TSRI patents and patent applications related to other potential drug compounds and technologies, including HIV/FIV protease inhibitors, aminoglycoside antibiotics, polysialytransferase, selectin inhibitors, nucleic acid binders, carbohydrate mimetics and osteoarthritis.

Under the four agreements with TSRI, we paid TSRI license fees consisting of an aggregate of 239,996 shares of our common stock with a deemed aggregate fair market value of $46,400, as determined on the dates of each such payment. Additionally, under each agreement, we owe TSRI royalties based on net sales by us, our affiliates and sublicensees of the covered products and royalties based on revenue we generate from sublicenses granted pursuant to the agreements. For the first licensed product under each of the four agreements, we also will owe TSRI payments upon achievement of certain milestones. In three of the four TSRI agreements, the milestones are the successful completion of a Phase 2 trial or its foreign equivalent, the filing of an NDA or its foreign equivalent and government marketing and distribution approval. In the remaining TSRI agreement, the milestones are the initiation of a Phase 3 trial or its foreign equivalent, the filing of an NDA or its foreign equivalent and government marketing and distribution approval. The aggregate potential amount of milestone payments we may be required to pay TSRI under all four TSRI agreements is approximately $14.0 million.

Each TSRI agreement terminates in part as follows: (i) with respect to each product which utilizes patent rights licensed under the agreement, on a country-by-country basis concurrently with the expiration of the last to expire of the applicable patent rights, (ii) with respect to each product which utilizes technology licensed under the agreement but which does not utilize patent rights also licensed thereunder, 15 years after the date of the first commercial sale of the product in each country and (iii) with respect to software licensed under the 1999 OPopS agreement, 75 years after the date the applicable copyright is filed in the United States.

Inc. Research, Inc. In November 2005, we entered into a master services agreement with Inc Research, Inc., formerly known as Advanced Biologics, as amended in January 2006. Under the terms of the agreement, Inc Research will, from time to time, at our request and pursuant to separate work orders, perform research and/or administrative services in connection with certain of our clinical trials, including trial management, data collection, statistical programming or analysis, quality assurance auditing, scientific and medical communications, regulatory affairs consulting, regulatory submissions and strategic consulting. Pursuant to the master services agreement, we have issued work orders totaling $34.0 million for services. Unless extended by the mutual agreement of the parties, the master services agreement will terminate on November 16, 2012. We may terminate the master services agreement at any time and for any reason, upon 30 days' prior notice to Inc Research.

NIH Small Business Innovation Research Awards. In June 2005, we received a National Institutes of Health Small Business Innovation Research Program Phase II Award in the amount of $612,000 from the National Institute of Allergy and Infectious Diseases, or NIAID. The award is to facilitate discovery of a new macrolide class of antibiotics through glycosylation, our proprietary chemistry technology, and evaluation of the lead compound in pre-clinical settings. The grant also contains a recommendation for future support in the amount of $575,000, which funds will be awarded subject to availability and the satisfactory progress of the project, as determined by the NIAID. The award originally provided funding support from July 1, 2005 through June 30, 2007 and was extended to May 31, 2008.

In September 2007, we received an award from NIAID in the amount of $1 million. The award will be used to conduct supplementary studies to the ongoing OPT-80 trials to confirm narrow spectrum activity and potency of OPT-80 against hypervirulent epidemic strains, to support additional toxicology and macrobiological studies to demonstrate the safety and efficacy of the OPT-80 compound and its major metabolite in CDI patients and to support a surveillance study of *C. difficile* isolates across North America to compare activity of OPT-80 with existing CDI treatments. The $1 million grant is renewable each year until August 2010 to a maximum of $3 million over a three year funding period.

Manufacturing

We rely on third parties to manufacture our product candidates and currently have no plans to develop our own manufacturing facility. We require in our manufacturing and processing agreements that all third-party contract manufacturers and processors produce APIs, and finished products in accordance with cGMP and all other applicable laws and regulations. We maintain confidentiality agreements with potential and existing manufacturers in order to protect our proprietary rights related to our drug candidates.

Par assigned to us its contract with Biocon to manufacture clinical trial supplies of the API for OPT-80 in February 2007 in connection with our repurchase of rights to OPT-80 for North America and Israel pursuant to the

prospective buy-back agreement with Par. The manufacturing facilities of Biocon have been approved by the FDA for other companies' drug products, however, Biocon's facilities have not yet been approved by the FDA for the manufacture of our OPT-80 drug supplies. We intend to contract with other third-party contract manufacturers for the commercial supply of OPT-80.

In June 2004, as part of our license agreement for exclusive rights to develop and commercialize Prulifloxacin in the United States, we entered into a supply agreement with Nippon Shinyaku for the manufacture and supply of the API for Prulifloxacin. In turn, Nippon Shinyaku contracts with Juzen Chemical Co. for the manufacture of the API for Prulifloxacin. The tablets used in our Phase 3 clinical trials for Prulifloxacin are manufactured by Angelini ACRAF, or Angelini. We are also in discussion with Angelini and other contract manufacturers for the manufacturing, packaging and labeling of Prulifloxacin for commercial sale in the United States. The manufacturing facilities of Juzen have been approved by the FDA for other companies' drug products; however, Juzen's facilities have not yet been approved for the manufacture of our Prulifloxacin drug supplies. Angelini's facilities have not been approved by the FDA for the manufacture of any drug.

We have used both in-house capabilities and outside third-party cGMP manufacturers for the preparation of compounds for pre-clinical development and for the manufacture of limited quantities of finished products for clinical development. We have developed a proprietary synthetic process in our laboratories for Globo-H, the carbohydrate portion of the OPT-822 cancer immunotherapy. Third parties with cGMP facilities have manufactured OPT-822 for clinical trials. We also plan to use third-party cGMP manufacturers for the production of the adjuvant, OPT-821, as well as for the production of our carbohydrate-based product candidate OPT-88, a disease-modifying intra-articular therapy for osteroarthritis.

Intellectual Property

The proprietary nature of, and protection for, our products, product candidates, processes and know-how are important to our business. We seek patent protection in the United States and internationally for our product candidates and other technology where available and when appropriate. Our policy is to patent or in-license the technology, inventions and improvements that we consider important to the development of our business. In addition, we use license agreements to selectively convey to others rights to our own intellectual property. We also rely on trade secrets, know-how and continuing innovation to develop and maintain our competitive position. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our technology. For this and more comprehensive risks related to our intellectual property, please see "Risk Factors — Risks Related to Our Intellectual Property."

We have established and continue to build proprietary positions for our pipeline product candidates and technology in the United States and abroad. We have built a portfolio of more than 90 patents and patent applications that we either own or have licensed around our key products and technologies. As of March 10, 2008, this portfolio included 14 issued U.S. patents and 13 pending U.S. patent applications. Foreign counterparts to these included 11 issued patents and 53 pending patent applications.

For our lead product candidate OPT-80, we have one pending patent cooperation treaty, or PCT, patent application and seven U.S. pending patent applications, and 22 pending foreign counterparts in Australia, Canada, China, Europe, Japan, South Korea, India, Taiwan, Mexico and Brazil. If issued, these OPT-80 related patent applications may cover the composition of matter, the specific crystalline polymorph forms, specific methods for manufacturing, methods of using and pharmaceutical formulations containing the various components. If issued, these patent applications would expire between 2023 and 2027. For our other product candidate Prulifloxacin, we have licensed one issued U.S. patent and one pending U.S. patent application from Nippon Shinyaku. The U.S. patent, which expires in 2009, covers the compound Prulifloxacin. If issued, the U.S. pending patent application for Prulifloxacin would expire in 2023 and may cover processes for producing a drug-form of Prulifloxacin. The remainder of our patents and patent applications, and licensed patents and patent applications, relate to our other products and technology, and expire between 2015 and 2023.

Government Regulation and Product Approval

FDA Approval Process

Regulation by governmental authorities in the United States and other countries is a significant factor in the development, manufacture and marketing of pharmaceuticals and antibiotics. All of our products will require regulatory approval by governmental agencies prior to commercialization. In particular, pharmaceutical drugs are subject to rigorous pre-clinical testing and clinical trials and other premarketing approval requirements by the FDA and regulatory authorities in other countries. In the United States, various federal, and, in some cases, state statutes and regulations, also govern or impact the manufacturing, safety, labeling, storage, record-keeping and marketing of pharmaceutical products. The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources. Regulatory approval, if and when obtained for any of our product candidates, may be limited in scope, which may significantly limit the indicated uses for which our product candidates may be marketed. Furthermore, approved drugs and manufacturers are subject to ongoing review and discovery of previously unknown problems that may result in restrictions on their manufacture, sale or use or in their withdrawal from the market.

Before testing any compounds with potential therapeutic value in human subjects in the United States, we must satisfy stringent government requirements for pre-clinical studies. Pre-clinical testing includes both *in vitro* and *in vivo* laboratory evaluation and characterization of the safety and efficacy of a drug and its formulation. Pre-clinical testing results obtained from studies in several animal species, as well as data from *in vitro* studies, are submitted to the FDA as part of an IND and are reviewed by the FDA prior to the commencement of human clinical trials. These pre-clinical data must provide an adequate basis for evaluating both the safety and the scientific rationale for the initial trials in human volunteers. In order to test a new drug in humans in the United States, an IND must be filed with the FDA. The IND will become effective automatically 30 days after receipt by the FDA, unless the FDA raises concern or questions about the conduct of the trials as outlined in the IND prior to that time. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed.

Clinical trials are typically conducted in three sequential phases, Phases 1, 2 and 3, with Phase 4 trials potentially conducted after initial marketing approval. These phases may be compressed, may overlap or may be omitted in some circumstances.

- *Phase 1.* After an IND becomes effective, Phase 1 human clinical trials may begin. These trials evaluate a drug's safety profile and the range of safe dosages that can be administered to healthy volunteers and/or patients, including the maximum tolerated dose that can be given to a trial subject with the target disease or condition. Phase 1 trials also determine how a drug is absorbed, distributed, metabolized and excreted by the body and the duration of its action. In some cases, we may decide to run what is referred to as a "Phase 1a" evaluation in which we administer single doses of a new drug candidate in a small group of people to evaluate its pharmacokinetic properties, safety, dose range and side effects. We may also decide to run what is referred to as a "Phase 1b" evaluation, which is a second safety-focused Phase 1 trial in which we administer a new drug candidate at its targeted dosing regimen in a small group of people to evaluate its pharmacokinetic properties, safety, dose range and side effects.

- *Phase 2.* Phase 2 clinical trials are typically designed to evaluate the potential effectiveness of the drug in patients and to further ascertain the safety of the drug at the dosage given in a larger patient population. In some cases, we may decide to run what is referred to as a "Phase 2a" evaluation, which is a trial to determine the ideal dosing regimen and length of treatment and to evaluate effectiveness and safety. We may also decide to conduct what is referred to as a "Phase 2b" evaluation, which is a second, confirmatory Phase 2 clinical trial in which we collect more efficacy and safety data prior to initiation of a Phase 3 clinical trial. If positive and accepted by the FDA, results from Phase 2b study can serve as a part of pivotal clinical trial in the approval of a drug candidate.

- *Phase 3.* In Phase 3 clinical trials, often referred to as pivotal clinical trials, the drug is usually tested in one or more controlled, randomized trials comparing the investigational new drug to an approved form of therapy or placebo in an expanded and well-defined patient population and at multiple clinical

sites. The goal of these trials is to obtain definitive statistical evidence of safety and effectiveness of the investigational new drug regimen as compared to a placebo or an approved standard therapy in defined patient populations with a given disease and stage of illness.

- *Phase 4.* Phase 4 clinical trials are studies required of or agreed to by a sponsor that are conducted after the FDA has approved a product for marketing. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication. These clinical trials are often referred to as Phase 3/4 post approval clinical trials. Failure to promptly conduct mandatory Phase 4 clinical trials could result in withdrawal of approval for products approved under accelerated approval regulations.

After completion of Phase 1, 2 and 3 clinical trials, if there is substantial evidence that the drug is safe and effective, an NDA is prepared and submitted for the FDA to review. The NDA must contain all of the essential information on the drug gathered to that date, including data from pre-clinical and clinical trials, and the content and format of an NDA must conform to all FDA regulations and guidelines. Accordingly, the preparation and submission of an NDA is a significant undertaking for a company. The FDA reviews all submitted NDAs before it accepts them for filing and may request additional information from the sponsor rather than accepting an NDA for filing. In this case, the NDA must be re-submitted with the additional information and, again, is subject to review before filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Most NDAs are reviewed by the FDA within ten months of submission. The review process is often significantly extended by the FDA through requests for additional information and clarification. The FDA may refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation but typically gives it great weight. If the FDA evaluations of both the NDA and the manufacturing facilities are favorable, the FDA may issue either an approval letter or an approvable letter, the latter of which usually contains a number of conditions that must be satisfied in order to secure final approval. If the FDA's evaluation of the NDA submission or manufacturing facility is not favorable, the FDA may refuse to approve the NDA or issue a not approvable letter.

Any products we manufacture or distribute under FDA approvals are subject to pervasive and continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the products. Drug manufacturers and their subcontractors are required to register with the FDA and, where appropriate, state agencies, and are subject to periodic unannounced inspections by the FDA and state agencies for compliance with cGMPs regulations which impose procedural and documentation requirements upon us and any third party manufacturers we utilize.

The FDA closely regulates the marketing and promotion of drugs. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available drugs for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use.

The FDA's policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our product candidates or approval of new indications after the initial approval of our existing product candidates. We cannot predict the likelihood, nature or extent of adverse governmental regulations that might arise from future legislative or administrative action, either in the United States or abroad.

We will also be subject to a wide variety of foreign regulations governing the development, manufacture and marketing of our products. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must still be obtained prior to manufacturing or marketing the product in those countries. The approval process varies from country to country and the time needed to secure approval may be longer or shorter than that required for FDA approval. We cannot assure you that clinical trials

conducted in one country will be accepted by other countries or that approval in one country will result in approval in any other country.

Fast Track Products Designation

The FDA has granted Fast Track status for OPT-80 in the treatment of CDI. The FDA's Fast Track program is intended to facilitate the development and expedite the review of drugs that are intended for the treatment of a serious or life-threatening condition for which there is no effective treatment and demonstrate the potential to address unmet medical needs for their condition. Under the Fast Track program, the sponsor of a new drug may request the FDA to designate the drug for a specific indication as a Fast Track product at any time during the clinical development of the product. The FDA must determine if the product qualifies for Fast Track designation within 60 days of receipt of the sponsor's request.

If Fast Track designation is obtained, the FDA may initiate review of sections of an NDA before the application is complete. This rolling review is available if the applicant provides a schedule for the submission of the remaining information and pays applicable user fees. However, the time period specified in the Prescription Drug User Fees Act, which governs the time period goals the FDA has committed to reviewing an application, does not begin until the complete application is submitted. The Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process. Participation in the Fast Track program does not eliminate any phase of clinical studies. Additionally, in some cases, a Fast Track designated product may also qualify for priority review, or review within a six-month time frame from the time an NDA is accepted for filing. A Fast Track designated product would ordinarily meet the FDA's criteria for priority review. We cannot guarantee any of our products with priority review designation, or if a priority designation is received, that review or approval will be faster than conventional FDA procedures.

Continuous Marketing Application

OPT-80 was also chosen to be the only investigational new drug in the FDA's CMA, Pilot 2 Program in the Division of Anti-infectives and Ophthalmology Products. The CMA designation offers several potential benefits, including a program of continuous FDA feedback designed to streamline the development process. In 2002, the FDA outlined the basic elements of two CMA pipeline programs: CMA Pilot 1 and CMA Pilot 2. Both programs apply only to certain new drug or biological products that have been designated as Fast Track products. CMA Pilot 1 provides for the review of a limited number of pre-submitted portions of an applicant's marketing application based on the terms and conditions agreed upon by the applicant and the FDA. Under the CMA Pilot 2 program in which we are a participant, the FDA and Fast Track drug applicants enter into an agreement to engage in frequent scientific feedback and interactions during the IND phase of product development. According to FDA guidelines, the CMA Pilot 2 program will evaluate the cost of such enhanced interaction between the FDA and applicants and whether it improves the efficiency and effectiveness of development programs, and will be limited to no more than one Fast Track product for each of 20 participating FDA review divisions. According to the FDA guidelines, CMA Pilot 2 applications are evaluated based on the FDA's overall assessment of (a) the potential value of enhanced interaction, emphasizing the potential public health benefit resulting from development of the product, (b) the likelihood that concentrated scientific dialogue will facilitate the availability of a promising novel therapy, and (c) the applicant's demonstration of commitment to product development as evidenced by a thorough consideration of the rationale for participation in CMA Pilot 2. Participation in the CMA Pilot 2 program does not in any way indicate product candidate efficacy or increase the likelihood of regulatory approval of the product candidate.

Hatch-Waxman Act

The key licensed patent under our agreement with Nippon Shinyaku covers Prulifloxacin for treating bacterial infections in humans and animals. This patent will expire in February 2009. We plan to apply to extend the term of this key patent under the Drug Price Competition and Patent Term Restoration Act, informally known as the Hatch-Waxman Act, which allows patent term extension of a maximum of five years, if certain conditions are met.

Competition

The pharmaceutical industry is highly competitive. We face significant competition from pharmaceutical companies and biotechnology companies that are researching and selling products designed to treat infectious disease. Many of these companies have significantly greater financial, manufacturing, marketing and product development resources than us. Additionally, many of these companies have substantially greater experience developing, manufacturing and commercializing drugs which may allow them to bring their products to market quicker than we can. Several pharmaceutical and biotechnology companies have already established themselves in the markets for the treatment of CDI and/or infectious diarrhea and many additional companies are currently developing products for the treatment of CDI and/or infectious diarrhea, which we expect will compete with OPT-80 and Prulifloxacin. Potentially significant competitors to OPT-80 and Prulifloxacin, both currently marketed and in clinical development, include the following:

Product	Stage of Development	Company
OPT-80 Competitors		
Flagyl™/metronidazole	Marketed	Pfizer, Sanofi-Aventis and generics
Vancocin™/oral vancomycin	Marketed	Viropharma and generics
Tolevamer™	Phase 3	Genzyme
Xifaxan™/rifaximin	Phase 3	Salix and generics
Alinia™/nitazoxanide	Phase 3	Romark
ramoplanin	Phase 2 completed	Oscient
CD Vaccine	Phase 1	Acambis
Prulifloxacin Competitors		
Cipro™/ciprofloxacin	Marketed	Bayer and generics
Zithromax™/azithromycin	Marketed	Pfizer
Xifaxan™/rifaximin	Marketed	Salix and generics
Bactrim™/Septra™/TMP/SMX	Marketed	Roche and generics
Vibramycin™/doxycycline	Marketed	Pfizer and generics
Dukoral™	Marketed	Novartis
Levaquin™/levofloxacin	Marketed	Johnson & Johnson
ACE527/ETEC Vaccine	Phase 2 completed	Iomai

Research and Development

Our research and development efforts are primarily focused on developing OPT-80 and Prulifloxacin and our other product candidates. Our research and development expense was approximately $41.6 million, $10.5 million and $7.0 million in years 2007, 2006 and 2005, respectively. Research and development expenses in 2007 include the one-time termination payment of $20 million related to the prospective buy-back agreement with Par, and the $1.9 million OPT-80 clinical supply material and active pharmaceutical ingredient which we purchased from Par.

Employees

As of March 10, 2008, we employed 47 persons, 18 of whom hold Ph.D., M.D. or DVM degrees. Nine employees were engaged in discovery research, thirteen in clinical research and regulatory affairs, four in commercial and corporate development and 21 in support administration, including finance, information systems, facilities and human resources. None of our employees is subject to a collective bargaining agreement. We consider our relations with our employees to be good.

Item 1a. Risk Factors

Risks Related to Our Business

We are a company with limited sources of revenue, and we are largely dependent on the success of our lead product candidate OPT-80 and, to a lesser degree, our other lead product candidate Prulifloxacin.

We are a biopharmaceutical company with no products approved for commercial sale and, to date, we have not generated any revenues from product sales. Our ability to generate future revenues depends heavily on our success in:

- developing and securing U.S. and/or foreign regulatory approvals for OPT-80 and Prulifloxacin and, to a lesser extent, other product candidates;
- commercializing any product candidates for which we receive approval from the FDA; and
- generating a pipeline of innovative product candidates utilizing our drug discovery platform or through licensing strategies.

Our product candidates will require extensive additional clinical study and evaluation, regulatory approval in multiple jurisdictions, substantial investment and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities. We have not submitted an NDA, or received marketing approval for either OPT-80 or Prulifloxacin, and we cannot be certain that either of these product candidates will be successful in clinical trials or receive regulatory approval. If we do not receive regulatory approval for and successfully commercialize OPT-80 and Prulifloxacin, we will not generate any revenues from product sales for several years, if at all, and we may not be able to continue our operations.

We believe our initial success will be more dependent on OPT-80 than Prulifloxacin, because we believe that our market for the treatment of CDI is larger than our market for the treatment of infectious diarrhea. Even if we successfully obtain regulatory approval to market OPT-80 or Prulifloxacin, our revenues for either drug candidate will be dependent upon the size of the markets in the territories for which we have commercial rights. If the markets for the treatment of CDI or infectious diarrhea are not as significant as we estimate, our business and prospects will be harmed.

We have incurred significant operating losses since inception and anticipate that we will incur continued losses for the foreseeable future.

We have experienced significant operating losses since our inception in 1998. As of December 31, 2007, we had an accumulated deficit of approximately $97.7 million. We have generated no revenues from product sales to date. We have funded our operations to date from the sale of approximately $154.8 million of our securities and through research funding pursuant to collaborations with partners or government grants. We expect to continue to incur substantial additional operating losses for the next several years as we advance our clinical trials and research and development initiatives and build our marketing and sales capabilities. Because of the numerous risks and uncertainties associated with developing and commercializing antibiotics, we are unable to predict the extent of any future losses. We may never successfully commercialize our product candidates and thus may never have any significant future revenues or achieve and sustain profitability.

If we fail to obtain additional financing, we may be unable to commercialize OPT-80 and Prulifloxacin or develop and commercialize our other product candidates, or continue our other research and development programs.

We will require additional capital to commercialize our current lead product candidates OPT-80 and Prulifloxacin. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may require us to pledge our assets as collateral or involve restrictive

covenants, such as limitations on our ability to incur additional indebtedness, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could negatively impact our ability to conduct our business. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates or one or more of our other research and development initiatives. We also could be required to:

- seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or

- relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

Any of the above events could significantly harm our business and prospects and could cause our stock price to decline.

We do not currently have sufficient resources to commercialize OPT-80 on our own. If we are unable to raise additional capital or we are unable to find a collaboration partner or are unable to effectively collaborate with one or more partners for the commercialization of OPT-80 or Prulifloxacin, we will not generate significant revenues from sales of OPT-80 and our business will be materially harmed.

We are dependent on third party collaborators and we may be unable to enter into future collaboration agreements or we may have disagreements with these collaborators.

We currently plan to build our own marketing and sales force for OPT-80 in North America and Prulifloxacin in the United States, and we may also seek one or more partners for the commercialization of OPT-80 outside of North America. We cannot be certain that we would be successful in attracting any such partners. If we were not able to find appropriate partners for the continued development and commercialization of OPT-80, we would either have to delay these initiatives which would harm our business and prospects, or raise significant additional funds to develop clinical and commercialization capabilities internally.

We are subject to a number of additional risks associated with our dependence on collaborations with third parties. Conflicts may arise between us and collaborators, such as conflicts concerning the interpretation of clinical data, the achievement of milestones, the interpretation of financial provisions or the ownership of intellectual property developed during the collaboration. If any such conflicts arise, a collaborator could act in its own self-interest, which may be adverse to our best interests. Any such disagreement between us and a collaborator could result in one or more of the following, each of which could delay or prevent the development or commercialization of OPT-80, and in turn prevent us from generating sufficient revenues to achieve or maintain profitability:

- reductions in the payment of royalties or other payments we believe are due pursuant to the applicable collaboration arrangement or agreement;

- uncertainties regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations and commercializing such rights;

- actions taken by a collaborator inside or outside our collaboration which could negatively impact our rights or benefits under our collaboration; or

- unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities.

In addition, a collaborator may shift its research, development, manufacturing and commercialization resources to other product opportunities including those that might be competitive with OPT-80.

If we cannot commercialize OPT-80, we will have to rely solely on Prulifloxacin and earlier stage product candidates for any future revenues, and our ability to achieve and sustain profitability will be materially and adversely harmed.

If we are unable to obtain FDA approval of our product candidates, we will not be able to commercialize them in the United States.

We need FDA approval prior to marketing our product candidates in the United States. If we fail to obtain FDA approval to market our product candidates, we will be unable to sell our product candidates in the United States, which will significantly impair our ability to generate any revenues.

This regulatory review and approval process, which includes evaluation of pre-clinical studies and clinical trials of our product candidates as well as the evaluation of our manufacturing processes and our third-party contract manufacturers' facilities, is lengthy, expensive and uncertain. To receive approval for a product candidate, we must, among other things, demonstrate with substantial evidence from well-controlled clinical trials that the product candidate is both safe and effective for each indication for which approval is sought. Satisfaction of the approval requirements typically takes several years and the time needed to satisfy them may vary substantially, based on the type, complexity and novelty of the pharmaceutical product. We cannot predict if or when we might receive regulatory approvals for any of our product candidates currently under development. Moreover, any approvals that we obtain may not cover all of the clinical indications for which we are seeking approval, or could contain significant limitations in the form of narrow indications, warnings, precautions or contra-indications with respect to conditions of use. In such an event, our ability to generate revenues from such products would be greatly reduced and our business would be harmed.

The FDA has substantial discretion in the approval process and may either refuse to consider our application for substantive review or may form the opinion after review of our data that our application is insufficient to allow approval of our product candidates. If the FDA does not consider or approve an application that we submit, it may require that we conduct additional clinical, pre-clinical or manufacturing validation studies and submit that data before it will reconsider our application. Depending on the extent of these or any other studies, approval of any applications that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be successful or considered sufficient by the FDA for approval or even to make our applications approvable. If any of these outcomes occur, we may be forced to abandon one or more of our future applications for approval, which might significantly harm our business and prospects.

It is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain the appropriate regulatory approvals necessary for us or our collaborators to commence product sales. Moreover, recent events, including complications arising from FDA-approved drugs such as Vioxx and Ketek, have raised questions about the safety of marketed drugs and may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new drugs based on safety, efficacy or other regulatory approvals. This increased scrutiny by regulatory authorities may result in significant delays in obtaining regulatory approvals, as well as more stringent product labeling and post-marketing testing requirements.

Although the FDA has granted Fast Track status to OPT-80 and selected it for participation in a CMA Pilot 2 Program, we cannot be certain that we will receive any benefits from these designations or that the designations will expedite regulatory review or approval of OPT-80. Participation in these programs will not eliminate any phase of clinical development. Moreover, our participation in the CMA Pilot 2 Program will involve frequent scientific discussions and other interactions with the staff of the FDA during the investigational new drug phase of our development of OPT-80. These frequent discussions could subject OPT-80 to a greater level of scrutiny than it might otherwise have received or require us to make more frequent submissions and endure other burdens that would have been avoided if we had not participated in the program. Therefore, despite any potential benefits of OPT-80's Fast Track and CMA Pilot 2 Program designations, significant uncertainty remains regarding the clinical development and regulatory approval process for OPT-80.

Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical testing is expensive and can take many years to complete, and its outcome is uncertain. Failure can occur at any time during the clinical trial process. The results of pre-clinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical testing. In addition, the type and amount of clinical data necessary to gain regulatory approval for our product candidates may change.

Even after we complete our planned clinical trials, our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the results of our clinical trials may not demonstrate to the satisfaction of or meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for any indication;
- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- the results of our clinical trials may not demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the results of our clinical trials may not demonstrate that a product candidate presents an advantage over existing therapies, or over placebo in any indications for which the FDA requires a placebo-controlled trial;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from pre-clinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a new drug application or other submission or to obtain regulatory approval in the United States or elsewhere; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Delays in clinical trials are common and have many causes, and any such delays could result in increased costs to us and jeopardize or delay our ability to achieve regulatory approval and commence product sales as currently contemplated.

We may experience delays in clinical trials of our product candidates. OPT-80 is currently in two Phase 3 clinical trials for the treatment of CDI. We anticipate enrollment in the first trial will be completed in the next few months and we anticipate completing enrollment and reporting data in the second trial in 2009. If both trials are successful, we intend to file an NDA as soon as practicable thereafter. In addition, we are planning to conduct clinical and proof-of-concept clinical trials for other indications of OPT-80. Prulifloxacin is in two Phase 3 trials for infectious diarrhea in travelers. We intend to conduct a Phase 4 trial of Prulifloxacin subsequent to NDA submission to compare Prulifloxacin to ciprofloxacin. We do not know whether planned clinical trials will begin on time, will need to be redesigned or will be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a trial, in reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, and clinical trial sites, in obtaining institutional review board approval at each site, in recruiting suitable patients to participate in a trial, in having patients complete a trial or return for post-treatment follow-up, in adding new sites or in obtaining sufficient supplies of clinical trial materials. Many factors affect patient enrollment, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the

clinical trial, competing clinical trials, clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating and whether the clinical trial design involves comparison to placebo. Several of our principal investigators have stated that the enrollment rate in the clinical trials for OPT-80 has been less than projected. Our original projections were based on enrollment rates for our Phase 2a trial of OPT-80. If we continue to experience lower than expected enrollment in the trials, the trials may not be completed as currently scheduled and we may incur delays in obtaining regulatory approval as well as additional significant expenses. Furthermore, with respect to the clinical trials conducted by third parties, we will have no control over their timing or success.

We could encounter delays if prescribing physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing antibiotics that have established safety and efficacy profiles or with administering placebo to patients in our placebo-controlled trials. Further, a clinical trial may be suspended or terminated by us, our collaborators, the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, our Prulifloxacin product candidate treats bacterial infections which tend to peak during high travel seasons. As a result, during certain times of the year, it is more difficult to enroll patients in our trials for Prulifloxacin. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects.

We may be required to suspend or discontinue clinical trials due to adverse events, adverse side effects or other safety risks that could preclude approval of our product candidates.

Our clinical trials may be suspended at any time for a number of reasons. We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants. In addition, regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to participants. In previous clinical trials of OPT-80, certain patients experienced non-drug related adverse events. Patients treated with Prulifloxacin have experienced drug-related side effects including abdominal pain, diarrhea, nausea, renal toxicities, cardiac arrhythmias, photosensitivity, rash, excessive flushing of the skin and central nervous system effects, such as seizures. The FDA recommended that we conduct a study to determine the effect, if any, of Prulifloxacin on the prolongation of the QT interval, a condition that is associated with potentially life-threatening cardiac arrhythmias. Our future clinical trials will involve testing in larger patient populations, which could reveal a high prevalence of these or other side effects. In such event, our trials would be interrupted, delayed or halted and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Even if we believe our product candidates are safe, our data is subject to review by the FDA, which may disagree with our conclusions and delay or deny approval of our product candidates which would significantly harm the commercial prospects of such product candidates. Moreover, we could be subject to significant liability if any volunteer or patient suffers, or appears to suffer, adverse side effects as a result of participating in our clinical trials. Any of these occurrences may significantly harm our business and prospects.

We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we and our collaborators may not be able to obtain regulatory approval for or commercialize our product candidates.

We have entered into agreements with third-party CROs, such as INC Research to provide monitors for and to manage data for our on-going clinical programs.

We and the CROs conducting clinical trials for our product candidates are required to comply with current good clinical practices, or GCPs, regulations and guidelines enforced by the FDA for all of our products in clinical development. The FDA enforces GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or the CROs conducting clinical trials of our product candidates fail to comply with applicable GCPs, the clinical data generated in the clinical trials may be deemed unreliable and the FDA may require additional clinical trials before approving any marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any clinical trials of our product candidates comply with GCPs. In addition, our clinical trials must be conducted with product produced under cGMP regulations, and will require a large number of test subjects. Our failure to comply with these regulations may require us to repeat clinical trials, which would be costly and delay the regulatory approval process and commercialization of our product candidates.

Typically, the CROs conducting clinical trials of our product candidates have the right to terminate their agreements with us or our collaborators upon notice in the event of an uncured material breach. In addition, some CROs have an ability to terminate their respective agreements with us if we fail to perform our obligations, if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. INC Research has been heavily involved in the clinical development and regulatory approval process for our lead product candidates and possesses significant experience with the regulatory process. We substantially rely on INC Research to conduct the clinical trials for OPT-80 and Prulifloxacin. INC Research has also subcontracted with other third-party CROs for various aspects of the clinical trials. If any relationships with INC Research or these other third-party CROs terminate, we or our collaborators may not be able to enter into arrangements with alternative CROs or we may enter into arrangements with alternative CROs that do not have the expertise or relationships that INC Research has with government agencies. For example, a third party service provider recently terminated their clinical trial agreement regarding the enrollment of patients in our Prulifloxacin trial in Guatemala. As a result, we are currently unable to recruit new patients in Guatemala and are evaluating additional sites to supplement existing ones in India and Mexico.

In addition, these third-party CROs are not our employees, and we cannot control whether or not they devote sufficient time and resources to our on-going clinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities, which could harm our competitive position. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements, or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

If we fail to gain and maintain approval from regulatory authorities in international markets for OPT-80 and any future product candidates for which we have rights in international markets, our market opportunities will be limited.

Sales of our product candidates outside of the United States will be subject to foreign regulatory requirements governing clinical trials and marketing approval. Even if the FDA grants marketing approval for a product candidate, comparable regulatory authorities of foreign countries must also approve the manufacturing and marketing of the product candidate in those countries. This is important for the commercialization of OPT-80 for which we currently have exclusive worldwide marketing rights. Obtaining foreign regulatory approvals could result in significant delays, difficulties and costs for us and require additional pre-clinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay the introduction of our products in those countries. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in others. Other than Prulifloxacin, which is sold by other parties in Japan, Italy and certain other European countries, none of our product candidates is approved for sale in any international market for which we have rights, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in our

international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to generate revenues will be diminished, which would significantly harm our business, results of operations and prospects.

We currently have no marketing and sales organization and have no experience in marketing drug products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenues.

We currently do not have a sales organization for the marketing, sales and distribution of pharmaceutical products. In order to commercialize any products, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. We plan to build our own marketing and sales force to commercialize OPT-80 in North America and will seek third-party partners outside North America. We own exclusive rights to commercialize Prulifloxacin in the United States, and we contemplate establishing our own sales force or seeking third-party partners to sell Prulifloxacin in the United States. The establishment and development of our own sales force to market any products we may develop will be expensive and time consuming and could delay any product launch, and we cannot be certain that we will be able to successfully develop this capability. We will also have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. To the extent we rely on third parties to commercialize our products, if any, we may receive less revenues than if we commercialized these products ourselves. In addition, we may have little or no control over the sales efforts of any third parties involved in commercializing our products. In the event we are unable to develop our own marketing and sales force or collaborate with a third-party marketing and sales organization, we would not be able to commercialize our product candidates which would negatively impact our ability to generate product revenues.

We may not be able to enter into acceptable agreements to market and commercialize OPT-80 outside of North America or if, needed, adequately build our own marketing and sales capabilities.

If appropriate regulatory approvals are obtained, we intend to commercialize OPT-80 outside of North America through collaboration arrangements with third parties. We may be unable to enter into collaboration arrangements in international markets. In addition, there can be no guarantee that if we enter into these collaboration arrangements with other parties that they will be successful or result in more revenues than we could obtain by marketing OPT-80 on our own. If we are unable to enter into collaboration arrangements for our products or develop an effective international sales force, our ability to generate product revenues would be limited, which would adversely affect our business, financial condition, results of operations and prospects. If we are unable to enter into such collaboration arrangements, we may need to develop our own marketing and sales force to market OPT-80 in a number of countries in Europe and Latin America to hospital-based and long-term care physicians. These efforts may not be successful as we have no relationships among such hospital-based and long-term care physicians. There is no guarantee that we will be able to develop an effective international sales force to successfully commercialize our products in these international markets.

If our product candidates are unable to compete effectively with branded and generic antibiotics, our commercial opportunity would be reduced or eliminated.

If approved, our lead product candidates will compete against both branded antibiotic therapies, such as Vancocin Pulvules with respect to OPT-80 and Xifaxan®/rifazamin with respect to Prulifloxacin, and generic antibiotics such as metronidazole and vancomycin with respect to OPT-80 and ciprofloxacin with respect to Prulifloxacin. In addition, we anticipate that OPT-80 will compete with other antibiotic and anti-infective product candidates currently in development for the treatment of CDI, such as Xifaxan®/rifaxamin, Alinia™/nitazoxanide and Tolevamer™. Many of these products have been or will be developed and marketed by major pharmaceutical companies, who have significantly greater financial resources and expertise in research and development, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals, manufacturing and marketing approved products than we do. As a result, these companies may obtain regulatory approval more rapidly than we are able to and may be more effective in selling and marketing their products as well. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

We anticipate that, if approved, OPT-80 and Prulifloxacin will face increasing competition in the form of generic versions of branded products of competitors that will lose their patent exclusivity. For example, OPT-80, if approved, will immediately face steep competition from an inexpensive generic form of metronidazole. OPT-80 currently faces generic oral vancomycin competition in Europe and may face competition from generic oral vancomycin in the United States in 2008. Generic antibiotic therapies typically are sold at lower prices than branded antibiotics and are generally preferred by managed care providers of health services. For example, because metronidazole is sold at such a low price, we believe it will be difficult to sell OPT-80 as a first-line therapy for the treatment of CDI. If we are unable to demonstrate to physicians and patients that, based on experience, clinical data, side-effect profiles and other factors, our products are preferable to these generic antibiotic therapies, we may never generate meaningful product revenues. In addition, many antibiotics experience bacterial resistance over time because of their continued use. There can be no guarantee that bacteria would not develop resistance to OPT-80, Prulifloxacin or any of our other product candidates. Our commercial opportunity would also be reduced or eliminated if our competitors develop and commercialize generic or branded antibiotics that are safer, more effective, have fewer side effects or are less expensive than our product candidates.

We currently depend, and will in the future continue to depend, on third parties to manufacture our product candidates, including OPT-80 and Prulifloxacin. If these manufacturers fail to provide us and our collaborators with adequate supplies of clinical trial materials and commercial product or fail to comply with the requirements of regulatory authorities, we may be unable to develop or commercialize our products.

We outsource all manufacturing of clinical trial supplies of our product candidates to third parties. We seek to establish long-term supply arrangements with third-party contract manufacturers. We intend to continue outsourcing the manufacture of our product candidates to third parties for any future clinical trials and large-scale commercialization of any product candidates that receive regulatory approval and become commercial drugs.

Our ability to develop and commercialize OPT-80 and Prulifloxacin and any other product candidates depends in part on our ability to arrange for collaborators or other third parties to manufacture our products at a competitive cost, in accordance with strictly enforced regulatory requirements and in sufficient quantities for clinical testing and eventual commercialization. We have not yet manufactured commercial batches of OPT-80, Prulifloxacin or any of our other product candidates. Collaborators or third-party manufacturers that we select to manufacture our product candidates for clinical testing or on a commercial scale may encounter difficulties with the small- and large-scale formulation and manufacturing processes required for such manufacture. Such difficulties could result in delays in clinical trials, regulatory submissions, or commercialization of our product candidates. The inability of us or our collaborators to enter into and maintain agreements with third-party manufacturers on acceptable terms would cause shortages of clinical trial supplies of our product candidates, thereby delaying or preventing regulatory approval and/or commercialization of the affected product candidate, and adversely affecting our ability to generate revenues. Further, development of large-scale manufacturing processes will require additional validation studies, which the FDA must review and approve. Even if we are able to establish additional or replacement manufacturers, identifying these sources and entering into definitive supply agreements and obtaining regulatory approvals may take a substantial amount of time and cost and such supply arrangements may not be available on acceptable economic terms.

In addition, we, our collaborators and other third-party manufacturers of our products must comply with current strictly enforced cGMP requirements enforced by the FDA through its facilities inspection program. These requirements include quality control, quality assurance and the maintenance of records and documentation. We rely on Biocon to manufacture OPT-80 API and rely on Patheon, Inc. to manufacture the drug product supplies. As such, Biocon and Patheon will be subject to ongoing periodic unannounced inspections by the FDA and other agencies for compliance with current cGMP, and similar foreign standards. We also rely on Nippon Shinyaku, which contracts with Juzen and Angelini, to manufacture Prulifloxacin drug supplies. The manufacturing facilities of Biocon, Juzen and Patheon have been inspected and approved by the FDA for other companies' drug products; however, neither Biocon's nor Juzen's nor Patheon's facilities have yet been approved for the manufacture of our drug supplies. Angelini's facilities have not been inspected or approved by the FDA. We or other third-party manufacturers of our products may be unable to comply with cGMP requirements and with other FDA, state, local and foreign regulatory requirements. We and our collaborators have little control over third-party manufacturers' compliance with these regulations and standards. A failure to comply with these requirements by our third-party manufacturers, including Biocon, Juzen, Angelini, and Patheon could result in the issuance of untitled letters and/or

warning letters from authorities, as well as sanctions being imposed on us, including fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall or withdrawal of product approval. In addition, we have no control over these manufacturers' ability to maintain adequate quality control, quality assurance and qualified personnel. If the safety of any quantities supplied by third parties is compromised due to their failure to adhere to applicable laws or for other reasons, we may not be able to obtain or maintain regulatory approval for or successfully commercialize one or more of our product candidates, which would significantly harm our business and prospects.

The commercial success of our product candidates will depend upon attaining significant market acceptance of these product candidates among physicians, patients, healthcare payors and the medical community.

Even if our product candidates are approved by the appropriate regulatory authorities for marketing and sale, physicians may not prescribe our product candidates, which would prevent us from generating revenues or becoming profitable. Market acceptance of OPT-80, Prulifloxacin and any of our future product candidates by physicians, patients and healthcare payors will depend on a number of factors, many of which are beyond our control, including:

- the clinical indications for which the product candidate is approved;
- acceptance by physicians and patients of each product candidate as a safe and effective treatment;
- perceived advantages over alternative treatments;
- the cost of treatment in relation to alternative treatments, including numerous generic antibiotics;
- the extent to which the product candidate is approved for inclusion on formularies of hospitals and managed care organizations;
- the extent to which bacteria develop resistance to the product candidate, thereby limiting its efficacy in treating or managing infections;
- whether the product candidate is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy for particular infections;
- the availability of adequate reimbursement by third parties, such as insurance companies and other healthcare payors;
- limitations or warnings contained in a product's FDA-approved labeling;
- relative convenience and ease of administration; and
- prevalence and severity of adverse side effects.

Because OPT-80 is a differentiated antibiotic for the treatment of CDI, it may encounter additional hurdles to market acceptance by physicians, who may be skeptical about its clinical benefits or healthcare payors who may resist reimbursing a premium-priced therapeutic particularly in light of the availability of generic alternatives.

We plan to target our marketing of Prulifloxacin primarily to high-prescribing physicians of antibiotics for travelers' diarrhea, including those at travel clinics. Because of the number of these physicians in the United States, we will be required to expend significant time and resources to obtain broad market acceptance of Prulifloxacin among these physicians. We do not have experience in marketing to this population of physicians and do not currently have the resources to be able to conduct such marketing efforts on our own. As such, we may not be successful in any of these marketing efforts which would limit the commercial success of Prulifloxacin. In addition, because Prulifloxacin has already been marketed by other companies to treat a wide range of bacterial infections, including infectious diarrhea, urinary tract infections, or UTIs and RTIs, patients may be able to obtain Prulifloxacin

from these other companies, and not from us, if Prulifloxacin is approved in the market where the patient is located. We have rights to Prulifloxacin only in the United States. These patients may obtain Prulifloxacin in these other markets from other companies even if these patients are from the United States.

If we fail to develop and commercialize other products or product candidates, we may be unable to grow our business.

A key element of our strategy is to commercialize a portfolio of new anti-infective products in addition to OPT-80 and Prulifloxacin. As a significant part of our growth strategy, we intend to develop and commercialize additional products and product candidates through our discovery research program using our proprietary technology, including OPopS. The success of this strategy depends upon our ability to identify, select and acquire pharmaceutical product candidates and products that fit into our development plans on terms that are acceptable to us.

Any product candidate we identify may require additional development efforts prior to commercial sale, including pre-clinical studies, extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and/or effective for approval by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives.

A significant portion of the research that we are conducting involves new and unproven technologies. Research programs to identify new disease targets and product candidates require substantial technical, financial and human resources whether or not we ultimately identify any candidates. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development.

If we are unable to develop suitable potential product candidates through internal research programs or by obtaining rights to novel therapeutics from third parties, our business and prospects will suffer.

Our focus on drug discovery and development using our technology platform, including our patented proprietary OPopS drug discovery platform, is novel and unique. As a result, we cannot be certain that our product candidates will produce commercially viable drugs that safely and effectively treat infectious diseases or other diseases. To date, our technology platform has yielded only a small number of anti-infective product candidates. In addition, we do not have significant clinical data with respect to any of these potential product candidates. Even if we are successful in completing clinical development and receiving regulatory approval for one commercially viable drug for the treatment of one disease using our technology platform and carbohydrate chemistry focus, we cannot be certain that we will also be able to develop and receive regulatory approval for other drug candidates for the treatment of other forms of that disease or other diseases. If we fail to develop and commercialize viable drugs using our platform and specialized focus, we will not be successful in developing a pipeline of potential product candidates to follow OPT-80 and Prulifloxacin, and our business prospects would significantly be harmed.

Our future growth depends on our ability to identify and acquire or in-license products. If we do not successfully identify and acquire or in-license related product candidates or integrate them into our operations, we may have limited growth opportunities.

We in-licensed the U.S. rights to Prulifloxacin from Nippon Shinyaku who, along with Meiji-Seika Kaisha Ltd., conducted the initial development of this product candidate. An important part of our business strategy is to continue to develop a pipeline of product candidates by acquiring or in-licensing products, businesses or technologies that we believe are a strategic fit for our business. Future in-licenses or acquisitions, however, may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;

- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. In particular, we may compete with larger pharmaceutical companies and other competitors in our efforts to establish new collaborations and in-licensing opportunities. These competitors likely will have access to greater financial resources than us and may have greater expertise in identifying and evaluating new opportunities. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts.

If we do not find collaborators for our future product candidates, we may be required to reduce or delay our rate of product development and commercialization and/or increase our expenditures.

Our strategy to develop and commercialize our product candidates in pre-clinical studies or early clinical trials includes entering into relationships with pharmaceutical or biotechnology companies to advance our programs. We may not be able to negotiate collaborations with these partners on acceptable terms. If we are unable to establish collaborative arrangements, we may be required to reduce or delay further development of some of our programs and/or increase our expenditures and undertake the development activities at our own expense.

If we are able to identify and reach agreement with collaborators for our product candidates, those relationships will also be subject to a number of risks, including:

- collaborators may not pursue further development and commercialization of product candidates resulting from our collaboration or may elect not to renew research and development programs;
- collaborators may delay clinical trials, underfund a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct additional clinical trials or require the development of a new formulation of a product candidate for clinical testing;
- a collaborator with marketing and distribution rights to one or more of our products may not commit sufficient resources to the marketing and distribution of our products, limiting our potential revenues from the commercialization of these products; and
- disputes may arise delaying or terminating the research, development or commercialization of our product candidates, or result in significant litigation or arbitration.

Even if we successfully establish collaborations or commercial agreements, these relationships may never result in the successful development or commercialization of any product candidates or the generation of sales or royalty revenues.

Our ability to pursue the development and commercialization of Prulifloxacin, our other product candidates and our future product candidates depends upon the continuation of our licenses from third parties.

Our license agreement with Nippon Shinyaku provides us with an exclusive license to develop and commercialize Prulifloxacin for any indication in the United States, with a right to sublicense to third parties. In the event Nippon Shinyaku is not able to supply us with Prulifloxacin, the license agreement provides us with a non-exclusive, worldwide right and license to manufacture or have Prulifloxacin manufactured for us. Either we or Nippon Shinyaku may terminate the license agreement immediately upon the bankruptcy or dissolution of the other party or upon a breach of any material provision of the agreement if the breach is not cured within 60 days following written notice. In addition, we are entitled to terminate the agreement in the event that the FDA compels us to cease sales of Prulifloxacin in the United States. If our license agreement with Nippon Shinyaku terminates, we will lose our rights to develop, manufacture and commercialize Prulifloxacin and our potential revenues would be limited. Similarly, if our agreement with TSRI for the license of our OPopS technology is terminated, we will not be able to further develop future product candidates using our OPopS technology.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability lawsuits related to the testing of our product candidates, and will face an even greater risk if product candidates are introduced commercially. An individual may bring a liability claim against us if one of our product candidates causes, or merely appears to have caused, an injury. If we cannot successfully defend ourselves against the product liability claim, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;
- injury to our reputation;
- termination of clinical trial sites or entire clinical trial programs;
- withdrawal of clinical trial participants;
- significant litigation costs;
- substantial monetary awards to or costly settlement with patients;
- product recalls;
- loss of revenues; and
- the inability to commercialize our product candidates.

We may become dependent upon consumer perceptions of us and the safety and quality of our product candidates. We could be adversely affected if we or our product candidates are subject to negative publicity. We could also be adversely affected if any of our potential products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to consumers. Also, because of our dependence upon consumer perceptions, any adverse publicity associated with illness or other adverse effects resulting from consumers' use or misuse of our potential products or any similar products distributed by other companies could have a material adverse impact on our results of operations.

We have global clinical trial liability insurance that covers our clinical trials up to a $10.0 million annual aggregate limit. Our current or future insurance coverage may prove insufficient to cover any liability claims brought against us. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for our product candidates, which would increase our insurance premiums. Because

of the increasing costs of insurance coverage, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise.

Even if we receive regulatory approval for our product candidates, we will be subject to ongoing significant regulatory obligations and oversight.

Even if we receive regulatory approval to sell our product candidates, the FDA and foreign regulatory authorities will likely impose significant restrictions on the indicated uses or marketing of such products, or impose ongoing requirements for potentially costly post-approval studies. In addition, following any regulatory approval of our product candidates, we and our collaborators will be subject to continuing regulatory obligations, such as requirements for storage, recordkeeping and safety reporting, and additional post-marketing obligations, including regulatory oversight of the labeling, packaging, promotion and marketing of our products. If we or our collaborators become aware of previously unknown problems with any of our product candidates in the United States or overseas or at our third-party manufacturers' facilities, a regulatory agency may impose restrictions on our products, our third-party manufacturers or on us, including requiring us to reformulate our products, conduct additional clinical trials, make changes in the labeling of our products, implement changes to, or obtain re-approvals of, our third-party manufacturers' facilities, or withdraw the product from the market. In addition, we or our collaborators may experience a significant drop in the sales of the affected products and our product revenues will be reduced, our reputation in the marketplace may suffer and we may become the target of lawsuits, including class action suits. Moreover, if we or our collaborators or third-party manufacturers fail to comply with applicable regulatory requirements, we may be subject to civil or criminal fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, costly new manufacturing requirements and criminal prosecution. Any of these events could harm or prevent sales of the affected products and reduce our related revenues or could substantially increase the costs and expenses of commercializing and marketing these products, which would significantly harm our business, financial condition and prospects.

If we fail to attract and retain senior management and key scientific personnel, we may be unable to successfully develop our product candidates, conduct our clinical trials and commercialize our product candidates.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. We are highly dependent upon our senior management and scientific staff, particularly Michael N. Chang, Ph.D., our President and Chief Executive Officer, Tessie M. Che, Ph.D., our Senior Vice President and Chief Operating Officer, Youe-Kong Shue, Ph.D., our Vice President, Clinical Development, Sherwood L. Gorbach, MD, our Vice President of Medical Affairs and Chief Medical Officer, and Kevin P. Poulos, our Chief Commercial Officer. The loss of services of any of Dr. Chang, Dr. Che, Dr. Shue or Mr. Poulos or one or more of our other members of senior management could delay or prevent the successful completion of our planned clinical trials or the commercialization of our product candidates. Replacing key employees may be difficult and costly and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop and commercialize products successfully. We do not maintain "key person" insurance policies on the lives of these individuals or the lives of any of our other employees. We employ these individuals on an at-will basis and their employment can be terminated by us or them at any time, for any reason and with or without notice.

We will need to hire additional personnel as we expand our clinical development and commercial activities. We may not be able to attract or retain qualified management and scientific personnel on acceptable terms in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the San Diego, California area. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will impede significantly the achievement of our research and development objectives, our ability to raise additional capital and our ability to implement our business strategy. In particular, if we lose any members of our senior management team, we may not be able to find suitable replacements, and our business and prospects may be harmed as a result.

We will need to increase the size of our organization, and we may experience difficulties in managing growth.

We are a small company with 47 employees as of March 10, 2008. To continue our clinical trials and commercialize our product candidates, we will need to expand our employee base for managerial, operational, marketing, sales, financial and other resources. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees and may take time away from running other aspects of our business, including development and commercialization of our product candidates. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

- manage our development efforts effectively;
- manage our current clinical trials for OPT-80 and Prulifloxacin effectively;
- integrate additional management, administrative and manufacturing personnel;
- build a marketing and sales organization; and
- maintain sufficient administrative, accounting and management information systems and controls.

We may not be able to accomplish these tasks, and accordingly, may not achieve our research, development and commercialization goals. Our failure to accomplish any of these goals could harm our financial results and prospects.

Third-party payor coverage and reimbursement may be insufficient or unavailable altogether for our product candidates, which could diminish our sales or affect our ability to sell our products profitably.

Market acceptance and sales of our product candidates will depend on reimbursement policies and may be affected by future healthcare reform measures. Government third-party payors, such as the Medicare and Medicaid programs, and private payors, including health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels for these drugs. Because third-party payors increasingly are challenging prices charged and the cost-effectiveness of medical products, significant uncertainty exists as to the ability of our product candidates to receive adequate coverage and reimbursement. We cannot be sure that third-party payors will place our product candidates on approved formularies or that reimbursement will be available in whole or in part for any of our product candidates. For example, the Deficit Reduction Act of 2005 requires an adjustment in Medicare payments for reimbursement of certain-hospital acquired conditions. The Centers for Medicare and Medicaid Services, or CMS, is likely to expand its list of non-payment for preventable hospital acquired infections. Both CDI and MRSA infections have been discussed but CMS has determined that further analysis is required before considering these conditions for non-reimbursement. Also, we cannot be sure that insufficient reimbursement amounts will not reduce the demand for, or the price of, our products, if approved.

Many healthcare providers, such as hospitals, receive a fixed reimbursement amount per procedure or other treatment therapy, and these amounts are not necessarily based on the actual costs incurred. As a result, these healthcare providers may choose only the least expensive therapies regardless of efficacy. We cannot guarantee that our product candidates will be the least expensive alternative and thus providers may decide not to use them or buy them for treatment.

We have not commenced efforts to have our product candidates reimbursed by government or third-party payors. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize our products successfully or at all, which would harm our business and prospects.

Recent proposed legislation may permit re-importation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could materially adversely affect our operating results and our overall financial condition.

We may face competition for our products from lower priced products from foreign countries that have placed price controls on pharmaceutical products. The Medicare Modernization Act of 2003, or MMA, contains provisions that may change U.S. importation laws and expand consumers' ability to import lower priced versions of our and competing products from Canada, where there are government price controls. These changes to U.S. importation laws will not take effect unless and until the Secretary of Health and Human Services certifies that the changes will lead to substantial savings for consumers and will not create a public health safety issue. The Secretary of Health and Human Services has not yet announced any plans to make the required certification. Even if the changes do not take effect, and other changes are not enacted, imports from Canada and elsewhere may continue to increase due to market and political forces, and the limited enforcement resources of the FDA, the U.S. Customs Service, and other government agencies. For example, Pub. L. No. 109-295, which was signed into law on October 4, 2006 and provides appropriations for the Department of Homeland Security for fiscal year 2007, expressly prohibits the U.S. Customs Service from using funds to prevent individuals from importing from Canada less than a 90-day supply of a prescription drug for personal use, when the drug otherwise complies with the Federal Food, Drug and Cosmetic Act. Further, several states and local governments have implemented importation schemes for their citizens, and, in the absence of federal action to curtail such activities, we expect other states and local governments to launch importation efforts. The importation of foreign products that compete with our own product candidates could negatively impact our business and prospects.

Current healthcare laws and regulations and future legislative or regulatory reforms to the healthcare system may affect our ability to sell our product candidates profitably.

In both the United States and certain foreign jurisdictions, there have been, and we anticipate there will continue to be, a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell our products profitably. In particular, the MMA added an outpatient prescription drug benefit to Medicare, the publicly-funded health insurance program in the United States generally for the elderly and disabled, which became effective on January 1, 2006. Drug benefits under this new benefit are administered through private plans that negotiate price concessions from pharmaceutical manufacturers. We cannot be certain that OPT-80 and Prulifloxacin or other current or future drug candidates will successfully be placed on the list of drugs covered by particular health plan formularies, nor can we predict the negotiated price for our drug candidates, which will be determined by market factors.

The MMA also changed the formula for determining payment for certain drugs, which include drugs provided in physician offices and other outpatient settings. Further, with respect to the Medicaid program, the Deficit Reduction Act of 2005 made changes to certain formulas used to calculate pharmacy reimbursement under Medicaid, the health insurance program in the United States generally for individuals and families with low incomes and resources, which became effective on January 1, 2007. These changes could lead to reduced payments to pharmacies. Many states have also created preferred drug lists and include drugs on those lists only when the manufacturers agree to pay a supplemental rebate. If OPT-80 and Prulifloxacin or other current or future drug candidates are not included on these preferred drug lists, physicians may not be inclined to prescribe them to their Medicaid patients, thereby diminishing the potential market for our products.

As a result of legislative proposals and the trend towards managed healthcare in the United States, third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new drugs. They may also refuse to provide any coverage of uses of approved products for medical indications other than those for which the FDA has granted market approvals. As a result, significant uncertainty exists as to whether and how much third-party payors will reimburse for newly-approved drugs, which in turn will put pressure on the pricing of drugs. Further, we do not have experience in ensuring approval by applicable third-party payors outside of the United States for reimbursement of our products. The availability of numerous generic antibiotics at lower prices than branded antibiotics can also be expected to substantially reduce the likelihood of reimbursement for OPT-80 and Prulifloxacin. We also anticipate pricing pressures in connection with the sale of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals.

We must comply with federal and state "fraud and abuse" laws, and, if we are unable to fully comply with such laws, we could face substantial penalties, which may adversely affect our business, financial condition and results of operations.

We are subject to various federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback laws and physician self-referral laws. Violations of these laws are punishable by criminal and civil sanctions, including, in some instances, exclusion from participation in federal and state healthcare programs, including Medicare and Medicaid, and the curtailment or restructuring of operations. We believe that our operations are in material compliance with such laws. However, because of the far-reaching nature of these laws, there can be no assurance that we would not be required to alter one or more of our practices to be in compliance with these laws. In addition, there can be no assurance that the occurrence of one or more violations of these laws or regulations would not result in a material adverse effect on our financial condition and results of operations.

Our business involves the use of hazardous materials and we and our third-party manufacturers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our third-party manufacturers' activities and, to a lesser extent, our own activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our manufacturers are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. Although we believe that the safety procedures for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. We currently have insurance coverage in the amount of approximately $250,000 for damage claims arising from contamination on our property. These amounts may not be sufficient to adequately protect us from liability for damage claims relating to contamination. If we are subject to liability exceeding our insurance coverage amounts, our business and prospects would be harmed. In the event of an accident, state or federal authorities may also curtail our use of these materials and interrupt our business operations.

Our business and operations would suffer in the event of computer, telecommunications or other system failure.

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our drug development programs. For example, the loss of clinical trial information from completed or ongoing clinical trials for OPT-80 or Prulifloxacin, which is maintained by our third-party CRO, could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability and the further development of our product candidates may be delayed.

Risks Related to Our Intellectual Property

It is difficult and costly to protect our intellectual property and our proprietary technologies, and we may not be able to ensure their protection.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of the use, formulation and structure of our product candidates, and the methods used to manufacture them, as well as successfully defending these patents against third-party challenges, including those from generic drug manufacturers. Our ability to protect our product candidates from unauthorized making, using, selling, offering to sell or importing by third parties is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date in the United States. The biotechnology patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our licensed patents, our patents or in third-party patents.

The degree of future protection for our proprietary rights is uncertain, because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of our pending patent applications or licensed patents, or for which we are not licensed under our license agreements;
- others may be able to make competing pharmaceutical formulations containing our product candidates or components of our product formulations that are either not covered by the claims of our licensed patents, not licensed to us under our license agreements or are subject to patents that expire;
- we or our licensors might not have been the first to make the inventions covered by our pending patent applications or the pending patent applications and issued patents of our licensors;
- we or our licensors might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent applications or our licensed patent applications will not result in issued patents;
- our pending patent applications or the pending patent applications and issued patents of our licensors may not provide us with any competitive advantages, may be designed around by our competitors, including generic drug companies, or may be held invalid or unenforceable as a result of legal challenges by third parties;
- we may not develop additional proprietary technologies that are patentable; or
- the patents of others may have an adverse effect on our business.

In addition, to the extent we are unable to obtain and maintain patent protection for one of our lead product candidates or in the event such patent protection expires, it may no longer be cost effective to extend our portfolio by pursuing additional development of a product candidate for follow-on indications.

While we have filed 7 patent applications for OPT-80, we do not yet have any issued patents for OPT-80.

These patent applications related to OPT-80 encompass various topics relating to:

- composition of matter for OPT-80;
- composition of matter for OPT-80 related substances and use for CDI;
- polymorphic crystalline forms;
- manufacturing processes;
- treatment of diseases;
- formulation; and
- OPT-80 related compounds (second generation).

If we are unable to obtain a composition of matter patent, our competitors, including generic drug companies, may be able to design other similar formulations of the active ingredient of OPT-80. Furthermore, even if these process and formulation patent applications become issued patents, our competitors, including generic drug companies, may be able to design around our manufacturing processes or formulation for OPT-80. As a result, our competitors may be able to develop competing products.

In addition, assuming our clinical trials are successful and completed in a timely manner, we currently plan to file a NDA for Prulifloxacin for the treatment of infectious diarrhea in travelers in 2009. However, the patent covering Prulifloxacin is scheduled to expire in February 2009, and due to this short remaining patent life we may be forced to abandon plans to pursue development and approval of Prulifloxacin for any indications, including infectious diarrhea. Although we also currently plan to apply for an extension of this patent term until 2014, we cannot assure you that the United States Patent and Trademark Office, or PTO, will grant the extension for the full additional five years, or at all. In either event, our business and prospects would be significantly harmed.

We depend, in part, on our licensors and collaborators to protect a portion of our proprietary rights. In such cases, our licensors and collaborators may be primarily or wholly responsible for the maintenance of patents and prosecution of patent applications relating to important areas of our business. For example, Nippon Shinyaku, SKI, TSRI and Cempra are responsible for the maintenance of patents and prosecution of patent applications relating to Prulifloxacin, OPT-822/OPT-821 combination therapy, our OPopS technology, and OPT-1068 also known as CEM-101, respectively. We may also be dependent on Par to provide technical support for patent applications relating to OPT-80. If any of these parties fail to adequately protect these product candidates with issued patents, our business and prospects would be significantly harmed.

Under our agreement with Nippon Shinyaku, in the event Nippon Shinyaku fails to take all steps necessary to seek extension of the patents licensed to us in the United States 180 days after we request such action be taken, then we have the right to take all necessary actions to extend the licensed patents. Our agreements with SKI, TSRI, Cempra and Par do not have explicit provisions regarding our rights to take necessary action with respect to maintenance of patents and prosecution of patent applications nor do such agreements provide us with any legal recourse in the event such parties do not so maintain and/or prosecute. If any of these parties fails to adequately maintain patents and prosecute patent applications relating to technology licensed to or from us, we may be required to take further action on our own to protect this technology. However, we may not be successful in maintaining such patents or prosecuting such patent applications and if so, our business and prospects would be significantly harmed.

We also rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third-party entity illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

If we or our licensors fail to obtain or maintain patent protection or trade secret protection for our product candidates or our technologies, third parties could use our proprietary information, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and attain profitability.

We may incur substantial costs as a result of litigation or other proceedings relating to our patent, trademark and other intellectual property rights, and we may be unable to protect our rights to, or use, our technology.

If we choose to go to court to stop someone else from using our inventions, that individual or company has the right to ask the court to rule that the underlying patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our rights to these patents.

Furthermore, a third party may claim that we or our manufacturing or commercialization partners are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making, using or selling our product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we or our commercialization partners are infringing the third party's patents and would order us or our partners to stop the activities covered by the patents. In addition, there is a risk that a court will order us or our partners to pay the other party damages for having violated the other party's patents. We have indemnified our commercial partners against patent infringement claims and thus would be responsible for any of their costs associated with such claims and actions. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use either do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

Although we have conducted searches of third-party patents with respect to OPT-80 and Prulifloxacin, these searches may not have identified all third-party patents relevant to those products and we have not conducted an extensive search of patents issued to third parties with respect to our other product candidates. Consequently, no assurance can be given that third-party patents containing claims covering our products, technology or methods do not exist, have not been filed, or could not be filed or issued. Because of the number of patents issued and patent applications filed in our technical areas or fields, we believe there is a risk that third parties may allege they have patent rights encompassing our products, technology or methods. In addition, we have not conducted an extensive search of third-party trademarks, so no assurance can be given that such third-party trademarks do not exist, have not been filed, could not be filed or issued, or could not exist under common trademark law. While we have filed a trademark application for the names "Optimer" and "Optimer Pharmaceuticals," we are aware that the name "Optimer" has been registered as a trademark with the PTO by more than one third party, including one in the biotechnology space. As such, we believe there is a significant risk that third parties may allege they have trademark rights encompassing the names for which we have applied for protection.

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our licensors' issued patents or our pending applications or our licensors' pending applications, or that we or our licensors were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our or our licensors' patent applications and could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the PTO, to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our U.S. patent position with respect to such inventions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

Risks Related to the Securities Market and Ownership of Our Common Stock

The market price of our common stock may be highly volatile.

Before our initial public offering in February 2007, there was no public market for our common stock. We cannot assure you that an active trading market will exist for our common stock. You may not be able to sell your shares quickly or at the market price if trading in our common stock is not active.

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including:

- announcement of FDA or comparable foreign regulatory agency approval or non-approval of our product candidates, or specific label indications for their use, or delays in the FDA or comparable foreign regulatory agency review process;
- actions taken by the FDA or other regulatory agencies with respect to our product candidates, clinical trials, manufacturing process or marketing and sales activities;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- the success of our development efforts and clinical trials, particularly with respect to OPT-80 and Prulifloxacin;
- announcements by our collaborators with respect to clinical trial results and communications from the FDA or comparable foreign regulatory agencies;
- the success of our efforts to acquire or in-license additional products or product candidates;
- developments concerning our collaborations and partnerships, including but not limited to those with our sources of manufacturing supply and our commercialization partners;
- actual or anticipated variations in our quarterly operating results;
- announcements of technological innovations by us, our collaborators or our competitors;
- new products or services introduced or announced by us or our commercialization partners, or our competitors and the timing of these introductions or announcements;
- third-party coverage or reimbursement policies;
- actual or anticipated changes in earnings estimates or recommendations by securities analysts;
- conditions or trends in the biotechnology and biopharmaceutical industries;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- general economic and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors;
- changes in the market valuations of similar companies;
- sales of common stock or other securities by us or our stockholders in the future;
- additions or departures of key scientific or management personnel;
- disputes or other developments relating to intellectual property, proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies; and
- trading volume of our common stock.

In addition, the stock market in general and the market for biotechnology and biopharmaceutical companies in particular have experienced extreme price and volume fluctuations that have often been unrelated and/or disproportionate to the operating performance of those companies. These broad market and industry factors may significantly harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could significantly harm our business, financial condition and prospects.

Future sales of our common stock in the public market could cause our stock price to decline.

Persons who were our stockholders prior to our initial public offering continue to hold a substantial number of shares of our common stock. Many of these stockholders are now able to sell their shares in the public market. Significant portions of these shares are held by a small number of stockholders. Sales by such stockholders of a substantial number of shares, or the expectation that such sales may occur, could significantly reduce the market price of our common stock. Moreover, the holders of a substantial number of shares of our common stock have rights, subject to certain conditions, to require us to file registration statements to permit the resale of their shares in the public market or to include their shares in registration statements that we may file for ourselves or other stockholders.

We have also registered all common stock that we may issue under our employee benefits plans. As a result, these shares can be freely sold in the public market upon issuance, subject to any applicable restrictions under the securities laws. In addition, our directors and executive officers may in the future establish programmed selling plans under Rule 10b5-1 of the Securities Exchange Act for the purpose of effecting sales of our common stock. If any of these events cause a large number of our shares to be sold in the public market, the sales could reduce the trading price of our common stock and impede our ability to raise future capital.

Negative conditions in the global credit markets may impair the liquidity of a portion of our investment portfolio.

Our investment securities consist of high-grade auction rate securities, money market funds, corporate debt securities and government agency securities. As of December 31, 2007, our short-term investments included $14.2 million of high-grade (AAA rated) auction rate securities issued primarily by municipalities and closed end funds. The recent negative conditions in the global credit markets have prevented some investors from liquidating their holdings, including their holdings of auction rate securities. As of March 21, 2008, we hold only two auction rate securities, representing approximately $1.5 million. There was insufficient demand at auction for these two auction rate preferreds. As a result, these affected securities are currently not liquid, and we could be required to hold them until they are redeemed by the issuer or to maturity. In the event we need to access the funds that are in an illiquid state, we will not be able to do so without a loss of principal, until a future auction on these investments is successful, the securities are redeemed by the issuer or they mature. At this time, management has not obtained sufficient evidence to conclude that these investments are impaired or that they will not be settled in the short term, although the market for these investments is presently uncertain. If the credit ratings of the security issuers deteriorate and any decline in market value is determined to be other-than-temporary, we would be required to adjust the carrying value of the investment through an impairment charge.

We will continue to incur significant costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we will continue to incur significant legal, accounting and other expenses. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the Securities and Exchange Commission, or SEC, and the Nasdaq Global Market, or Nasdaq, impose various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, these rules and regulations to make it more difficult and more expensive for us to maintain director and officer liability insurance, and we may be required to incur substantial costs in the future to maintain the same or similar coverage.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In fiscal 2008, we will be required to perform system and process evaluation and testing of our internal controls over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we may need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. We currently have five employees dedicated full-time to accounting and finance matters. In the future we will hire full-time employees in the accounting and finance department, as necessary, to ensure we have effective internal controls over financial reporting and disclosure controls and procedures. We also hire consultants from time to time to address these matters. If we are unable to hire adequate accounting and finance personnel, we may not be able to meet our public company reporting and governance obligations, including those set forth under the Sarbanes-Oxley Act. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which would require additional financial and management resources.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us, even if doing so would benefit our stockholders, or remove our current management. These provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- a requirement of approval of not less than 662/3% of all outstanding shares of our capital stock entitled to vote to amend any bylaws by stockholder action, or to amend specific provisions of our certificate of incorporation;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with a stockholder owning 15% or more of our outstanding voting stock for a

period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Such a delay or prevention of a change of control transaction could cause the market price of our stock to decline.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our facilities currently consist of approximately 18,000 square feet of space, approximately 65% of which is laboratory space and approximately 35% of which is office space, located at our corporate headquarters in San Diego, California. The current facilities are leased through November 2011, with an option to lease additional space and two options to extend the term for an additional five years each through November 2021. We believe these facilities are adequate to meet our current needs and that additional space will be available on commercially reasonable terms as needed.

Item 3. Legal Proceedings

We are not currently a party to any legal proceeding.

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

No matters were submitted to a vote of security holders during the fourth quarter of fiscal year ended December 31, 2007.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock has been traded on the Nasdaq Global Market under the symbol "OPTR" since February 9, 2007. Prior to that time, there was no public market for the common stock. The following table sets forth the range of high and low sale prices for the common stock for each completed fiscal quarter since February 9, 2007.

2007	High	Low
First Quarter (from February 9, 2007)	$ 10.74	$ 7.24
Second Quarter	$ 10.40	$ 8.50
Third Quarter	$ 10.42	$ 7.75
Fourth Quarter	$ 8.86	$ 6.50

As of March 10, 2008, there were approximately 125 holders of record of our common stock.

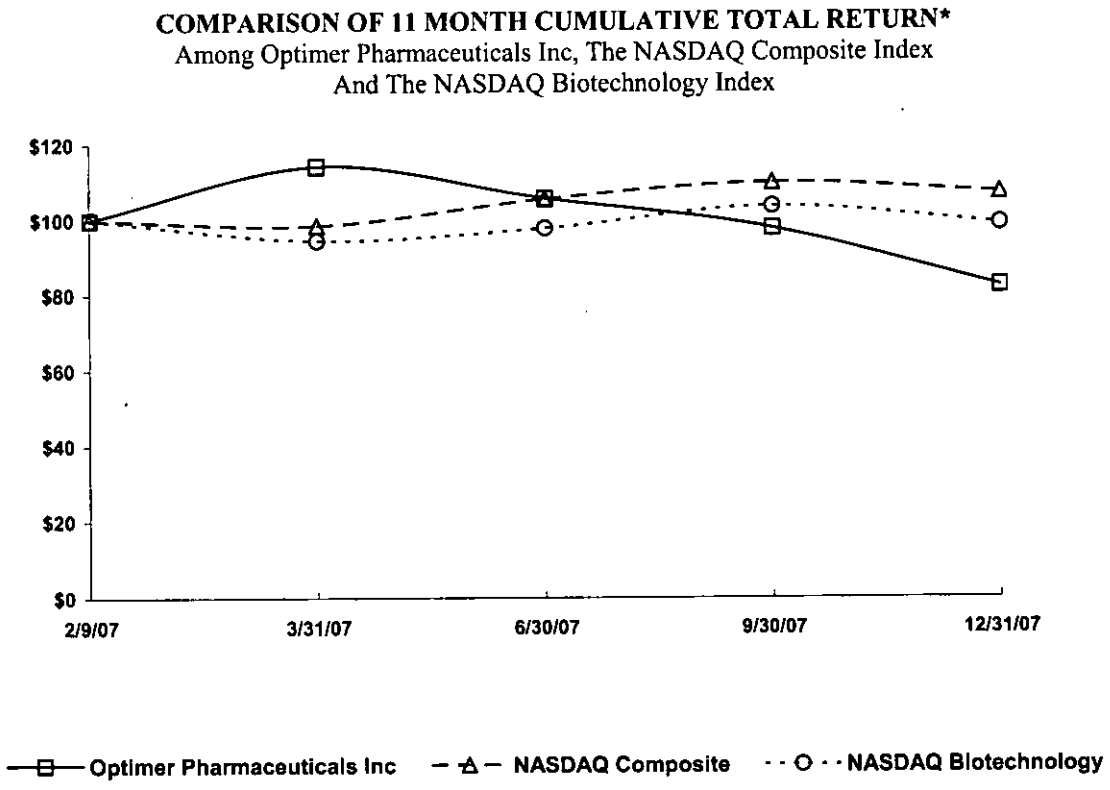
Dividends

We have never paid or declared cash dividends on our capital stock. We currently intend to retain future earnings, if any, for use in the expansion and operation of our business and do not anticipate paying any cash dividends in the foreseeable future.

Performance Measurement Comparison (1)

The following graph shows the total stockholder return of an investment of $100 in cash on February 9, 2007 in (i) the Company's common stock, (ii) the Nasdaq Composite Index (the "Nasdaq") and (iii) the Nasdaq Biotechnology Index. All values assume reinvestment of the full amount of all dividends.

Comparison of Cumulative Total Return on Investment since our Initial Public Offering on February 9, 2007:



* $100 invested on 2/9/07 in stock or 1/31/07 in index-including reinvestment of dividends. Fiscal year ending December 31.

(1) This section is not "soliciting material", is not deemed "filed" with the SEC, is not subject to the liabilities of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and is not to be incorporated by reference in any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

Repurchases of Equity Securities

We did not repurchase any shares of our common stock during the fourth quarter of fiscal year ended December 31, 2007.

Item 6. Selected Consolidated Financial Data

You should read the following selected consolidated financial and operating information together with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and notes thereto included elsewhere in this report. Historical results for any prior period are not necessarily indicative of the results to be expected for any future period.

	Years Ended December 31,				
	2007	2006	2005	2004	2003
	(in thousands, except per share amounts)				
Statement of Operations Data:					
Collaboration and grant revenues	$ 767	$ 933	$ 2,147	$ 1,111	$ 542
Operating expenses:					
Research and development	41,569	10,481	7,047	8,571	7,910
Marketing	2,048	—	—	—	—
General and administrative	5,351	3,523	2,782	2,697	2,856
Total operating expenses	48,968	14,004	9,829	11,268	10,766
Loss from operations	(48,201)	(13,071)	(7,682)	(10,157)	(10,224)
Interest income (expense) and other, net	2,062	1,169	237	247	441
Net loss	(46,139)	(11,902)	(7,445)	(9,910)	(9,783)
Accretion to redemption amount of redeemable convertible preferred stock	—	(329)	(223)	(12)	(13)
Net loss attributable to common stockholders	$ (46,139)	$ (12,231)	$ (7,668)	$ (9,922)	$ (9,796)
Basic and diluted net loss per share attributable to common stockholders:	$ (2.12)	$ (4.81)	$ (3.22)	$ (4.76)	$ (5.01)
Weighted average shares outstanding:	21,715	2,543	2,383	2,084	1,954

	As of December 31,				
	2007	2006	2005	2004	2003
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 58,806	$ 21,341	$ 29,880	$ 1,953	$ 11,134
Working capital	52,173	17,990	28,490	1,231	10,349
Total assets	60,786	24,114	32,335	4,903	14,837
Redeemable convertible preferred stock	—	65,460	65,078	32,175	32,163
Accumulated deficit	(97,698)	(51,558)	(39,656)	(32,212)	(22,302)
Total stockholders' equity (deficit)	52,903	(46,702)	(35,143)	(28,463)	(18,760)

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

The following discussion and analysis should be read in conjunction with our "Selected Consolidated Financial Data" and consolidated financial statements and accompanying notes appearing elsewhere in this report. This discussion and other parts of this report may contain forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under "Risk Factors" and elsewhere in this report.

Overview

We are a biopharmaceutical company focused on discovering, developing and commercializing innovative anti-infective products. Our initial development efforts address products that treat gastrointestinal infections and related diseases where current therapies have limitations, including limited efficacy, serious adverse side effects, drug-to-drug interactions, difficult patient compliance and bacterial resistance.

We currently have two late-stage anti-infective product candidates, OPT-80 and Prulifloxacin. OPT-80, our lead product candidate, is an antibiotic currently in two Phase 3 registration trials for the treatment of *Clostridium difficile*-infections, or CDI, also known as *Clostridium difficile*-associated disease, or CDAD, the most common nosocomial, or hospital acquired, diarrhea. In April 2005, we entered into a collaboration agreement with Par Pharmaceutical, Inc., or Par, pursuant to which we and Par, exclusively collaborated in the clinical development and commercialization of OPT-80. In February 2007, we elected to terminate the collaboration agreement with Par, exercised our right under a prospective buy-back agreement to repurchase Par's rights to develop and commercialize OPT-80 in North America and Israel and paid Par a one-time $20.0 million termination fee. As a result, we now hold worldwide rights to OPT-80. The Food and Drug Administration, or FDA, has granted Fast Track status for OPT-80 in the treatment of CDI. Fast Track designation indicates that OPT-80 has the potential to treat life-threatening diseases with unmet medical needs. The FDA also chose OPT-80 to be the only investigational new drug in the Continuous Marketing Applications, or CMA, Pilot 2 Program in the Division of Anti-Infective and Ophthalmology Products. The CMA designation offers several potential benefits, including a program of continuous FDA feedback designed to streamline the development process. Participation in these programs will not eliminate any phase of clinical development. Prulifloxacin is an antibiotic currently in two Phase 3 trials for the treatment of travelers' diarrhea, a form of infectious diarrhea caused by bacteria. We will seek a label for Prulifloxacin for the treatment of infectious diarrhea in travelers and initially plan to focus commercialization efforts on the treatment of travelers' diarrhea. Prulifloxacin is a prodrug in the fluoroquinolone class of antibiotics, a widely-used class of broad-spectrum antibiotics. We are developing additional product candidates using our proprietary technology, including our OPopS drug discovery platform.

We were incorporated in November 1998. Since inception, we have focused on developing our product candidates, including OPT-80 and Prulifloxacin. We have never been profitable and have incurred significant net losses since our inception. As of December 31, 2007, we had an accumulated deficit of $97.7 million. These losses have resulted principally from costs incurred in connection with research and development activities, including the costs of clinical trial activities associated with our current lead product candidates, license fees and general and administrative expenses. We expect to continue to incur operating losses for the next several years as we pursue the clinical development and commercialization of our product candidates, as well as acquire or in-license additional products or product candidates, technologies or businesses that are complementary to our own.

Financial Operations Overview

Collaboration and Grant Revenues

We have not generated any revenues from sales of commercial products. Since inception, we have generated revenues primarily as a result of various collaborations with pharmaceutical and biotechnology companies and grants from government agencies. We may also periodically recognize as revenues non-refundable payments for achieving certain milestones, during the term of our collaboration agreements.

Research and Development Expense

Research and development expense consists of expenses incurred in connection with identifying and developing our drug candidates and developing and advancing our drug discovery technology. Our research and development expenses consist primarily of salaries and related employee benefits, costs associated with clinical trials managed by our CROs and costs associated with non-clinical research activities and regulatory approvals. Our most significant costs are for clinical trials, including payments to vendors such as CROs, investigators, manufacturers of clinical supplies and related consultants. Our historical research and development expenses have resulted predominantly from our clinical trials of OPT-80 and Prulifloxacin, the development of our carbohydrate technology platform, including OPopS, in-licensing fees and general research activities. We charge all research and development expenses to operations as they are incurred because the underlying technology associated with these expenditures relates to our research and development efforts and has no alternative future uses. From inception through December 31, 2007, we incurred total research and development expenses of approximately $84.3 million.

We use our internal research and development resources across several projects, and much of this use which is not allocable to a specific project. Accordingly, we do not account for all of our internal research and development costs on a project basis. In addition to our internal resources, we use external service providers and vendors to conduct our clinical trials, to manufacture our product candidates to be used in clinical trials and to provide various other research and development related products and services. These external costs are allocable to specific projects.

External costs are expensed as incurred. We incurred $34.4 million, $4.8 million and $46.1 million of research and development expenses directly related to the development of OPT-80 for the years ended December 31, 2007 and 2006, and cumulatively through December 31, 2007, respectively. We incurred $4.0 million, $2.5 million, and $8.7 million of research and development expenses directly related to the development of Prulifloxacin for the years ended December 31, 2007 and 2006, and cumulatively through December 31, 2007, respectively. All other research and development expenses were for other clinical programs.

We expect our research and development expenses to increase substantially as we expand our clinical trial activities with respect to OPT-80 and Prulifloxacin, advance our other product candidates through the development process and invest in additional product opportunities and research programs. Clinical trials and pre-clinical studies are time-consuming and expensive. Our expenditures on current and future pre-clinical and clinical development programs are subject to many uncertainties. We test our product candidates in several pre-clinical studies, and we then conduct clinical trials for those product candidates that we determine to be the most promising. As we obtain results from clinical trials, we may elect to discontinue or delay trials for some product candidates in order to focus our resources on more promising product candidates. Completion of clinical trials may take several years and the length of time generally varies substantially according to the type, size of trial and intended use of a product candidate. The cost of clinical trials may vary significantly over the life of a project as a result of a variety of factors, including:

- the number of patients who participate in the trials;
- the number of sites included in the trials;
- the length of time required to enroll trial participants;
- the duration of patient treatment and follow-up;
- the costs of producing supplies of the product candidates needed for clinical trials and regulatory submissions; and
- the costs, requirements and timing of, and the ability to secure, regulatory approvals.

As a result of the uncertainties discussed above, we are unable to determine with any significant degree of certainty the duration and completion costs of our research and development projects or when and to what extent we

will generate revenues from the commercialization and sale of any of our product candidates. However, while we do not have specific estimates for the costs of all of our projects, we currently estimate that we will incur external costs of approximately $13.7 million to complete the Phase 3 clinical trials for OPT-80 to treat CDI and approximately $3.6 million to complete the Phase 3 clinical trials for Prulifloxacin to treat infectious diarrhea in travelers.

General and Administrative Expense

General and administrative expense consists primarily of compensation, including stock-based compensation, and other expenses related to an allocated portion of facility cost, legal fees and other professional services expenses, our corporate administrative employees and insurance costs. We anticipate that we will maintain our existing level of general and administrative expenditures. However, we will make determinations as to the necessary levels of general and administrative expenditures on an on-going basis in response to our research and development activities and regulatory obligations.

Interest Income (Expense) and Other, Net

Interest income (expense) and other, net consists of interest earned on our cash, cash equivalents and short-term investments and other-than-temporary declines in the market value of available-for-sale securities and cash and non-cash interest charges related to bridge financings.

Net Operating Losses and Tax Credit Carryforwards

As of December 31, 2007, we had federal, state and foreign net operating loss carryforwards of approximately $87.6 million, $86.3 million and $2.0 million, respectively. If not utilized, the net operating loss carryforwards will begin expiring in 2020 for federal purposes and 2012 for state purposes. The foreign losses originate from our subsidiary in Taiwan. The losses from our subsidiary in Taiwan expire five years after origination. As of December 31, 2007, we had both federal and state research and development tax credit carryforwards of approximately $1.8 million and $1.3 million, respectively. The federal tax credits will begin expiring in 2020 unless previously utilized and the state tax credits carryforward indefinitely. As of December 31, 2007, we had a state manufacturer's investment tax credit carryforward of approximately $103,000 which will begin to expire in 2011, unless previously utilized. Under Section 382 of the Internal Revenue Code of 1986, as amended, substantial changes in our ownership may limit the amount of net operating loss and tax credit carryforwards that could be utilized annually in the future to offset taxable income. Any such annual limitation may significantly reduce the utilization of the net operating losses and tax credits before they expire. We are in the process of completing a Section 382 study at this time. In each period since our inception, we have recorded a valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset has not met the "more likely than not" threshold required under SFAS 109, Accounting For Income Taxes. As a result, we have not recorded any federal or state income tax benefit in our statement of operations.

Critical Accounting Policies and Estimates

Our Management's Discussion and Analysis of our Financial Condition and Results of Operations is based on our consolidated financial statements, which have been prepared in conformity with generally accepted accounting principles in the United States. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and related disclosures. Actual results could differ from those estimates. While our significant accounting policies are described in more detail in Note 1 of the Notes to Consolidated Financial Statements appearing elsewhere in this report, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

Our collaboration agreements contain multiple elements, including non-refundable upfront fees, payments for reimbursement of third-party research costs, payments for ongoing research, payments associated with achieving specific development milestones and royalties based on specified percentages of net product sales, if any. We apply

the revenue recognition criteria outlined in Staff Accounting Bulletin, or SAB, No. 104, *Revenue Recognition* and Emerging Issues Task Force, or EITF, Issue 00-21, *Revenue Arrangements with Multiple Deliverables*, or EITF 00-21. In applying these revenue recognition criteria, we consider a variety of factors in determining the appropriate method of revenue recognition under these arrangements, such as whether the elements are separable, whether there are determinable fair values and whether there is a unique earnings process associated with each element of a contract.

Cash received in advance of services being performed is recorded as deferred revenue and recognized as revenue as services are performed over the applicable term of the agreement.

When a payment is specifically tied to a separate earnings process, revenues are recognized when the specific performance obligation associated with the payment is completed. Performance obligations typically consist of significant and substantive milestones. Revenues from milestone payments may be considered separable from funding for research services because of the uncertainty surrounding the achievement of milestones for products in early stages of development. Accordingly, these milestone payments are allowed to be recognized as revenue if and when the performance milestone is achieved if they represent a substantive earnings process as described in EITF 00-21.

In connection with certain research collaboration agreements, revenues are recognized from non-refundable upfront fees, which we do not believe are specifically tied to a separate earnings process, ratably over the term of the agreement or the period over which we have significant involvement or perform services. Research fees are recognized as revenue as the related research activities are performed.

Revenues derived from reimbursement of direct out-of-pocket expenses for research costs associated with grants are recorded in compliance with EITF Issue 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent*, and EITF Issue 01-14, *Income Statement Characterization of Reimbursements Received for "Out-of-Pocket" Expenses Incurred.* According to the criteria established by these EITF Issues, in transactions where we act as a principal, with discretion to choose suppliers, bear credit risk and perform part of the services required in the transaction, we record revenue for the gross amount of the reimbursement. The costs associated with these reimbursements are reflected as a component of research and development expense in the consolidated statements of operations.

None of the payments that we have received from collaborators to date, whether recognized as revenue or deferred, are refundable even if the related program is not successful.

Research and Development

Research and development costs are expensed as incurred and consist primarily of costs associated with clinical trials, compensation, including stock-based compensation, and other expenses related to research and development, including personnel costs, facilities costs and depreciation.

When nonrefundable payments for goods or services to be received in the future for use in research and development activities are made, we apply the criteria outlined in EITF Issue 07-3, or EITF 07-3, *Accounting for Non-Refundable Advance Payments for Goods or Services to be Used in Future Research and Development Activities* . In accordance with EITF 07-3, these types of payments are deferred and capitalized. The capitalized amounts are expensed when the related goods are delivered or the services are performed.

Accrued Clinical Trial Costs

A substantial portion of our on-going research and development activities are performed under agreements we enter into with external service providers, including CROs, who conduct many of our research and development activities. We accrue the costs incurred under these contracts based on factors such as estimates of work performed, milestones achieved, patient enrollment and costs historically incurred for similar contracts. As actual costs become known, we adjust our accruals. To date, our accruals have been within management's estimates, and no material adjustments to research and development expenses have been recognized. We expect to significantly expand the level of research and development activity to be performed by external service providers and our estimated accruals

will be more material to our future operations. Subsequent changes in estimates may result in a material change in our accruals, which could also materially affect our results of operations.

Stock-Based Compensation

Effective January 1, 2006, we adopted Statement of Financial Accounting Standards, or SFAS, No. 123(R), *Share-Based Payment*, which revises SFAS No. 123, *Accounting for Stock-Based Compensation* and supersedes Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*. SFAS No. 123(R) requires that share-based payment transactions with employees be recognized in the financial statements based on their fair value and recognized as compensation expense over the vesting period. We used the modified prospective method when we adopted SFAS No. 123(R) and accordingly we did not restate the results of operations for the prior periods. Compensation expense of $1.2 million and $0.7 million was recognized in the years ended December 31, 2007 and 2006, respectively, for all awards granted on or after December 31, 2005 as well as for the unvested portion of awards granted before December 31, 2005.

Stock-based compensation expense is estimated as of the grant date based on the fair value of the award and is recognized as expense over the requisite service period, which generally represents the vesting period. We estimate the fair value of our stock options using the Black-Scholes option-pricing model and the fair value of our stock awards based on the quoted market price of our common stock.

Estimating the fair value for stock options requires judgment, including estimating stock-price volatility, expected term, expected dividends and risk-free interest rates. The expected volatility rates are based on the historical fluctuation in the stock price since inception. The average expected term is calculated using SAB No. 107, "*Simplified Method for Estimating the Expected Term.*" Expected dividends are estimated based on our dividend history as well as our current projections. The risk-free interest rate for periods approximating the expected terms of the options is based on the U.S. Treasury yield curve in effect at the time of grant. These assumptions are updated on an annual basis or sooner if there is a significant change in circumstances that could affect these assumptions.

Equity instruments issued to non-employees are recorded at their fair value as determined in accordance with SFAS No. 123(R) and EITF Issue 96-18, *Accounting for Equity Instruments That are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods and Services*, and are periodically revalued as the equity instruments vest and are recognized as expense over the related service period.

Results of Operations

Comparison of Years Ended December 31, 2007 and 2006

Collaboration and Grant Revenues. Collaboration and grant revenues for the years ended December 31, 2007 and 2006 were $767,000 and $933,000, respectively. The decrease of $166,000, or 18%, was primarily due to a decrease in revenue from a NIH grant and the conclusion of a development and license agreement, partially offset by an increase of $370,000 related to a collaboration with a natural healthcare company.

Research and Development Expense. Research and development for the years ended December 31, 2007 and 2006 was $41.6 million and $10.5 million, respectively. The increase of $31.1 million, or 297% was due primarily to the $20.0 million payment to Par to reacquire the rights to OPT-80 in North America and Israel, the advancement of our OPT-80 and Prulifloxacin clinical trials, including the initiation of the second pivotal Phase 3 trial for OPT-80, and the purchase of $1.9 million of OPT-80 clinical supply material and active pharmaceutical ingredient for the OPT-80 clinical study.

Marketing. We incurred $2.0 million of marketing expense in the year ended December 31, 2007 and no such expense in the year ended December 31, 2006. The expenses in the year ended December 31, 2007 were related to salaries and pre-launch activities which include medical education, scientific conferences, and public relations services.

General and Administrative Expense. General and administrative expense for the year ended December 31, 2007 and 2006 was $5.3 million and $3.5 million, respectively. The increase of $1.8 million, or 52%, was due to

increased expenses to support a public company infrastructure which included higher legal expenses, insurance and compensation expenses, including a $679,000 of stock compensation expense, an increase of $265,000 over the prior year.

Interest Income and Other, net. Net interest income and other for the year ended December 31, 2007 and 2006 were $2.1 million and $1.2 million, respectively. The increase was primarily due to higher cash and short-term investment balances as a result of our initial public offering completed in February 2007 and our private placement offering which closed in October 2007.

Comparison of Years Ended December 31, 2006 and 2005

Collaboration and Grant Revenues. Collaboration and grant revenues for the years ended December 31, 2006 and 2005 were $933,000 and $2.1 million, respectively. The decrease of $1.2 million, or 57%, was primarily due to a decrease in revenue from NIH grants, which generated $494,000 in the current year versus $1.1 million in the prior year. In addition, we terminated the manufacturing supply agreement with Sloan-Kettering Institute for Cancer Research as well as our development and license agreement with a pharmaceutical company. These two agreements generated an additional $265,000 and $225,000 of revenue, respectively, in the prior year.

Research and Development Expense. Research and development expense for the years ended December 31, 2006 and 2005 were $10.5 million and $7.0 million, respectively. The increase of $3.5 million, or 50%, was primarily due to costs incurred on our OPT-80 Phase 2b/3 and Prulifloxacin Phase 3 clinical trials which we initiated in May 2006 and July 2006, respectively.

General and Administrative Expense. General and administrative expense for the years ended December 31, 2006 and 2005 were $3.5 million and $2.8 million, respectively. The increase of $741,000, or 27% was primarily due to stock compensation expense of $415,000 recorded in accordance with FAS 123(R) and the forgiveness of a note receivable to an officer of $263,000.

Interest Income and Other, Net. Net interest income and other for the years ended December 31, 2006 and 2005 were $1.2 million and $237,000, respectively, an increase of $932,000 from the prior year. The increase was primarily due to higher cash and short-term investment balances resulting in an increase in interest income of $663,000, as well as a decrease in interest expense of $239,000 related to the fair value of warrants and the related beneficial conversion feature, in connection with our bridge financing that was expensed in 2005.

Liquidity and Capital Resources

Sources of Liquidity

Since inception, our operations have been financed primarily through the sale of equity securities. Through March 10, 2008, we received gross proceeds of approximately $154.8 million from the sale of shares of our preferred and common stock as follows:

- in May 2000, we sold a total of 1.6 million shares of Series A preferred stock for proceeds of $3.4 million;
- from March 2001 to December 2001, we sold a total of 4.1 million shares of Series B preferred stock for proceeds of $32.2 million;
- in April 2005, we sold a total of 1.5 million shares of Series C preferred stock for proceeds of $12.0 million;
- from April 2005 to November 2005, we sold a total of 2.9 million shares of Series D preferred stock for proceeds of $22.3 million;
- in February 2007, we sold a total of 7.0 million shares of our common stock in connection with our initial public offering for proceeds of $49.0 million; and

- in October 2007, we sold a total of 4.6 million shares of our common stock in connection with a private placement offering for proceeds $35.9 million.

Until required for operations, we invest a substantial portion of our available funds in money market funds, corporate debt securities, United States government instruments and other readily marketable debt instruments, all of which are investment-grade quality. We have established guidelines relating to diversification and maturities of our investments to preserve principal and maintain liquidity.

Cash Flows

As of December 31, 2007, cash, cash equivalents and short-term investments totaled approximately $58.8 million as compared to $21.3 million as of December 31, 2006, an increase of approximately $37.5 million. In 2007, we raised $43.6 million in net proceeds from our initial public offering and $33.6 million in net proceeds from a private placement. We also paid Par $20.0 million of the net proceeds to reacquire rights to OPT-80 in North America and Israel.

We cannot be certain if, when or to what extent we will receive cash inflows from the commercialization of our product candidates. We expect our development expenses to be substantial and to increase over the next few years as we advance the development of our product candidates.

In April 2005, we entered into a collaboration agreement with Par pursuant to which we and Par exclusively collaborated to develop and commercialize OPT-80. We had granted to Par an exclusive royalty-bearing license, with the right to sublicense, promote, market, distribute and sell OPT-80 in a territory composed of the United States, Canada and Puerto Rico, with an option to extend the territory to include Israel. We retained all other rights to OPT-80 in the rest of the world. In January 2007, we entered into a prospective buy-back agreement with Par which provided us with an option to terminate the collaboration and repurchase the rights to develop and commercialize OPT-80 in North America and Israel.

In February 2007, we elected to terminate the collaboration agreement pursuant to the prospective buy-back agreement with Par and repurchased the rights to develop and commercialize OPT-80 in North America and Israel. We now hold worldwide rights to OPT-80. Under the terms of the prospective buy-back agreement, we paid Par a one-time $20.0 million termination fee and purchased $1.9 million of OPT-80 clinical supply material and active pharmaceutical ingredient. We are also obligated to pay Par a one-time $5.0 million milestone payment, a 5% royalty on net sales by us or our affiliates of OPT-80 in North America and Israel, and a 1.5% royalty on net sales by us or our affiliates of OPT-80 in the rest of the world. In addition, in the event we license our right to market OPT-80 in the rest of the world, we will be required to pay Par a 6.25% royalty on net revenues we receive related to OPT-80. We are obligated to pay each of these royalties, if any, on a country-by-country basis for seven years commencing on the applicable commercial launch in each such country.

In June 2004, we entered into a license agreement with Nippon Shinyaku to which we acquired the non-exclusive right to import and purchase Prulifloxacin , and the exclusive right (with the right to sublicense), within the United States, to develop, make, use, offer to sell, sell and license products suitable for consumption by humans containing Prulifloxacin. Additionally, we acquired rights within the United States to a key patent which covers the compound and the treatment of bacterial infections in humans and animals. Under the terms of the agreement, we will be required to pay Nippon Shinyaku a milestone payment in the amount of $1.0 million upon the filing, if any, of the NDA for the Prulifloxacin in the United States.

Funding Requirements

Our future capital uses and requirements depend on numerous factors including, but not limited to, the following:

- the progress of our clinical trials, including expenses to support the trials and the milestone payments that may become payable to Par and Nippon Shinyaku;

- our ability to establish and maintain strategic collaborations, including licensing and other arrangements;
- the costs involved in prosecuting, enforcing or defending patent claims or other intellectual property rights;
- the costs and timing of regulatory approvals;
- the costs of establishing sales or distribution capabilities;
- the commercial success of our products; and
- the extent to which we in-license, acquire or invest in other indications, products, technologies and businesses.

We believe that our existing cash and cash equivalents will be sufficient to meet our capital requirements for at least the next 12 months.

Until we can generate significant cash from our operations, we expect to continue to fund our operations with existing cash resources that were primarily generated from of offerings of our equity securities and collaborations and government grants. In addition, we may finance future cash needs through the sale of additional equity securities, strategic collaboration agreements and debt financing. However, we may not be successful in entering into additional collaboration agreements, in receiving milestone or royalty payments under new or existing collaboration agreements, in obtaining new government grants or in obtaining equity or debt financing. In addition, we cannot be sure that our existing cash and investment resources will be adequate, that financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or our stockholders. Having insufficient funds may require us to delay, scale-back or eliminate some or all of our development programs, relinquish some or even all of our rights to product candidates at an earlier stage of development or renegotiate less favorable terms than we would otherwise choose. Failure to obtain adequate financing also may adversely affect our ability to operate as a going concern. If we raise funds by issuing equity securities, substantial dilution to existing stockholders would likely result. If we raise funds by incurring additional debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

Off-Balance Sheet Arrangements

We have not engaged in any off-balance sheet activities.

Contractual Obligations

The following table describes our long-term contractual obligations and commitments as of December 31, 2007:

	Payments Due by Period				
	Total	Less than 1 year	1-2 years	3-5 years	After 5 years
			(in thousands)		
Operating lease obligation	$ 2,887	$ 784	$ 1,477	$ 626	$ —

We have contracted with a contract research organization, or CRO, for clinical research services for the OPT-80 Phase 3 clinical trials and Prulifloxacin Phase 3 clinical trials. We have issued purchase orders totaling $34.0 million for these services, $20.4 million of which were issued in 2006 and an additional $9.8 million of which were issued in 2007. As of December 31, 2007, we have paid $12.5 million related to these purchase orders. We can terminate the service agreement at any time upon 60 days' written notice to the CRO. We have not included any amounts related to the CRO contract in the table above.

The contractual obligations table does not include (a) a potential future milestone payment in the amount of $1.0 million to Nippon Shinyaku due upon filing our first NDA in the United States for Prulifloxacin, (b) potential future milestone payments to Cempra in the amount of $1.0 million due upon the regulatory approval of each of the first two products we develop under our licensing agreement with Cempra in any country which is a member of the Association of Southeast Asian Nations, or ASEAN, (c) potential future milestone payments to SKI for each product licensed under the SKI agreement as follows: (i) $500,000 upon the commencement of Phase 3 clinical studies, (ii) $750,000 upon the filing of the first NDA, (iii) $1.5 million upon marketing approval in the United States and (iv) $1.0 million upon marketing approval in each and any of Japan and certain European countries, (d) potential future milestone payments of up to $14.0 million to TSRI due upon achievement of certain clinical milestones, the filing of NDAs or their foreign equivalents and government marketing and distribution approval, or (e) a future $5.0 million milestone payment to Par upon the earliest occurrence of (i) the successful completion by us of our pivotal Phase 3 trial for OPT-80, (ii) our grant to a third party of the rights to OPT-80 or (iii) the submission to the FDA of a NDA for OPT-80. We may also be required to pay royalties on any net sales of Prulifloxacin, OPT-80 and other licensed product candidates. The milestone and royalty payments under our license agreements are not included in the table above because we cannot, at this time, determine when or if the related milestones will be achieved or the events triggering the commencement of payment obligations will occur.

Recently Issued Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board, or FASB, issued FASB Statement No. 157, "*Fair Value Measurements*", or SFAS 157, which defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 applies to other accounting pronouncements that require or permit fair value measurements. The new guidance is effective for financial statements issued for fiscal years beginning after November 15, 2007, and for interim periods within those fiscal years. We are currently evaluating the impact of SFAS 157, but do not believe the adoption of this standard will have a material impact on our consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, "*The Fair Value Option for Financial Assets and Liabilities*", or SFAS 159. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. SFAS 159 will be effective for our fiscal year beginning after November 15, 2007. Early adoption is permitted. We are currently evaluating the impact of SFAS 159, but do not believe the adoption of this standard will have a material impact on our financial position, cash flows, and results of operations.

In July 2007, the FASB released Emerging Issues Task Force Issue 07-3, "*Accounting for Nonrefundable Advance Payments for Goods or Services to be used in Future Research and Development Activities*", or EITF 07-3. In accordance with EITF 07-3, nonrefundable advance payments for goods or services to be received in the future for use in research and development activities should be deferred and capitalized. The capitalized amounts should be expensed as the related goods are delivered or the services are performed. EITF 07-3 is effective for new contracts entered into during fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. Our current accounting treatment is consistent with EITF 07-3 and as such this EITF is not expected to have an impact on its financial position, cash flows, and results of operations.

In December 2007, the FASB issued Statement of Financial Accounting Standards, or SFAS No. 160, "*Noncontrolling Interests in Consolidated Financial Statements — An Amendment of ARB No. 51*", or SFAS 160. SFAS 160 requires the recognition of a noncontrolling interest, sometimes called minority interest, as equity in the consolidated financial statements and separate from the parent's equity. The amount of net income attributable to the noncontrolling interest will be included in consolidated net income on the face of the income statement. SFAS 160 clarifies that changes in a parent's ownership interest in a subsidiary that do not result in deconsolidation are equity transactions if the parent retains its controlling financial interest. In addition, this statement requires that a parent recognize a gain or loss in net income when a subsidiary is deconsolidated. Such gain or loss will be measured using the fair value of the noncontrolling equity investment on the deconsolidation date. SFAS 160 also includes expanded disclosure requirements regarding the interests of the parent and its noncontrolling interest. SFAS 160 is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. Earlier adoption is prohibited. We have not determined the impact, if any, that adopting this standard may have on our financial position, cash flows, and results of operations.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Our cash and cash equivalents and short-term investments as of December 31, 2007 consisted primarily of money market funds and government agency securities. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are in short-term marketable securities. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. A hypothetical ten percent change in interest rates during the year ended December 31, 2007 would have resulted in approximately a $207,000 change in net loss. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our securities portfolio. In general, money market funds are not subject to market risk because the interest paid on such funds fluctuates with the prevailing interest rate.

Item 8. Financial Statements and Supplementary Data

Our financial statements required by this item are attached to this Report beginning on page 61.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this report, an evaluation was performed under the supervision and with the participation of our management, including our chief executive officer and chief financial officer (collectively, our "certifying officers"), of the effectiveness of the design and operation of our disclosure controls and procedures. Based on their evaluation, our certifying officers concluded that these disclosure controls and procedures are effective in providing reasonable assurance that the information required to be disclosed by us in our periodic reports filed with the SEC is recorded, processed, summarized and reported within the time periods specified by the SEC's rules and SEC reports.

We believe that a controls system, no matter how well designed and operated, is based in part upon certain assumptions about the likelihood of future events, and therefore can only provide reasonable, not absolute, assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

In addition, we have reviewed our internal controls over financial reporting and have made no changes during the quarter ended December 31, 2007, that our certifying officers concluded materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. Our 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 accounting principles generally accepted in the United States of America.

Our internal control over financial reporting is supported by written policies and procedures that pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and disposition of our assets' provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles and that our receipts and expenditures are being made only in accordance with authorizations of our management and our Board or Directors;

and provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statement.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. 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.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2007. We based this assessment on criteria for effective internal control over financial reporting described in "Internal Control-Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Our assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of its internal control over financial reporting. We reviewed the results of our assessment with the Audit Committee.

Based on this assessment, management determined that, as of December 31, 2007, our internal control over financial reporting was effective to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

This report does not include an attestation report of Ernst & Young, our registered public accounting firm regarding internal control over financial reporting. Our report was not subject to attestation by Ernst & Young pursuant to temporary rules of the Securities and Exchange Commission that permit us to provide only management's report in this report.

Item 9B. Other Information

None.

PART III

Certain information required by Part III is omitted from this report because we will file a definitive proxy statement within 120 days after the end of our fiscal year ended December 31, 2007 pursuant to Regulation 14A (the "Proxy Statement") for our annual meeting of stockholders to be held on May 28, 2008, and certain information included in the Proxy Statement is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance

We have adopted a Code of Business Conduct and Ethics that applies to all officers, directors and employees. The Code of Business Conduct and Ethics is available on our website at www.optimerpharma.com. If we make any substantive amendments to the Code of Business Conduct and Ethics or grant any waiver from a provision of the Code to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website. We will promptly disclose on our website (i) the nature of any amendment to the policy that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals, the name of such person who is granted the waiver and the date of the waiver.

The other information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

Item 11. Executive Compensation

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

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

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

Item 14. Principal Accountant Fees and Services

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

1. *Financial Statements*

See Index to Consolidated Financial Statements of this report.

2. *Financial Statement Schedules*

None.

3. Exhibits

Exhibit No.		Description of Document
3.1	(3)	Certificate of Incorporation of Optimer Pharmaceuticals, Inc., as amended and restated.
3.2	(7)	Bylaws of Optimer Pharmaceuticals, Inc., as amended.
4.1	(4)	Common Stock Certificate of Optimer Pharmaceuticals, Inc.
4.2	(1)	Investors' Rights Agreement by and among Optimer Pharmaceuticals, Inc. and certain stockholders of the registrant dated November 30, 2005, as amended and restated.
4.3	(6)	Registration Rights Agreement, dated October 23, 2007, by and between Optimer Pharmaceuticals, Inc. and the purchasers listed on the signature pages thereto.
10.1	(1)*	Master Service Agreement between Optimer Pharmaceuticals, Inc. and Advanced Biologics, LLC, dated November 16, 2005, as amended by the Addendum to the Master Services Agreement between Optimer Pharmaceuticals, Inc. and Advanced Biologics, LLC, dated January 16, 2006.
10.2	(1)	Grant to Optimer Pharmaceuticals, Inc. by The National Institutes of Health dated June 1, 2005.
10.3	(3)*	Collaboration Research and Development and License Agreement between Optimer Pharmaceuticals, Inc. and Cempra Pharmaceuticals, Inc., dated March 31, 2006.
10.4	(4)*	Agreement between Optimer Pharmaceuticals, Inc. and Sloan-Kettering Institute for Cancer Research dated July 31, 2002, as amended by the First Amendment to License Agreement between Optimer Pharmaceuticals, Inc. and Sloan-Kettering Institute for Cancer Research dated June 30, 2005.
10.5	(3)*	License Agreement between Optimer Pharmaceuticals, Inc. and Nippon Shinyaku Co., Ltd., dated June 10, 2004.

10.6	(1)*	License Agreement between Optimer Pharmaceuticals, Inc. and The Scripps Research Institute dated July 23, 1999.
10.7	(1)*	License Agreement between Optimer Pharmaceuticals, Inc. and The Scripps Research Institute dated May 30, 2001.
10.8	(1)*	License Agreement between Optimer Pharmaceuticals, Inc. and The Scripps Research Institute dated May 30, 2001.
10.9	(1)*	License Agreement between Optimer Pharmaceuticals, Inc. and The Scripps Research Institute dated June 1, 2004.
10.10	(3)	Building Lease between Optimer Pharmaceuticals, Inc. and Pacific Sorrento Technology Park dated May 1, 2001, as amended by the First Amendment to Building Lease between Optimer Pharmaceuticals, Inc. and Pacific Sorrento Technology Park dated July 12, 2001.
10.11	(1)+	Form of Employee Proprietary Information Agreement of Optimer Pharmaceuticals, Inc.
10.12	(1)+	Employment Agreement between Optimer Pharmaceuticals, Inc. and Michael N. Chang dated June 17, 2005.
10.13	(1)+	Offer letter between Optimer Pharmaceuticals, Inc. and Sherwood L. Gorbach dated October 6, 2005.
10.14	(1)+	Offer letter between Optimer Pharmaceuticals, Inc. and Kevin P. Poulos dated June 15, 2006.
10.15	(1)+	Offer letter between Optimer Pharmaceuticals, Inc. and John D. Prunty dated May 10, 2006.
10.16	(1)+	Offer letter between Optimer Pharmaceuticals, Inc. and Tessie M. Che dated August 30, 2001.
10.17	(1)+	Offer letter between Optimer Pharmaceuticals, Inc. and Youe-Kong Shue dated February 18, 2000.
10.18	(1)+	Form of Indemnification Agreement between Optimer Pharmaceuticals, Inc. and its directors and officers.
10.19	(1)+	1998 Stock Plan of Optimer Pharmaceuticals, Inc.
10.20	(1)+	Stock Plan Stock Option Agreement of Optimer Pharmaceuticals, Inc.
10.21	(3)+	2006 Equity Incentive Plan of Optimer Pharmaceuticals, Inc.
10.22	(7)+	Employee Stock Purchase Plan of Optimer Pharmaceuticals, Inc., as amended.
10.23	(3)	Prospective Buy-Back Agreement between Optimer Pharmaceuticals, Inc. and Par Pharmaceutical, Inc. dated January 19, 2007.
10.24	(5)*	Supply Agreement with Biocon Limited dated August 29, 2005, as amended on July 6, 2006 by the Agreement to Amend Supply Agreement dated August 29, 2005 (Amendment 1).
10.25	(5)*	Assignment letter between Par Pharmaceutical, Inc. and Biocon Limited dated January 16, 2007.
10.26	(8)	Summary of Optimer Pharmaceuticals, Inc. 2008 Incentive Compensation Plan.
23.1		Consent of Independent Registered Public Accounting Firm.
31.1		Certification of principal executive officer required by Rule 13a-14(a) or Rule 15d-14(a).
31.2		Certification of principal financial officer required by Rule 13a-14(a) or Rule 15d-14(a).
32		Certification by the Chief Executive Officer and the Chief Financial Officer of Optimer Pharmaceuticals, Inc., as required by Rule 13a-14(b) or 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).

\+ Indicates management contract or compensatory plan.

* Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

(1) Filed with Registrant's Registration Statement on Form S-1 on November 9, 2006.

(2) Filed with Registrant's Amendment No. 2 to Registration Statement on Form S-1 on January 5, 2007.

(3) Filed with Registrant's Amendment No. 3 to Registration Statement on Form S-1 on January 22, 2007.

(4) Filed with Registrant's Amendment No. 4 to Registration Statement on Form S-1 on February 5, 2007.

(5) Filed with the Registrant's Current Report on Form 8-K on February 26, 2007.

(6) Filed with the Registrant's Current Report on Form 8-K on October 29, 2007.

(7) Filed with the Registrant's Current Report on Form 8-K on September 18, 2007.

(8) Filed with the Registrant's Current Report on Form 8-K on March 17, 2008.

SIGNATURES

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

OPTIMER PHARMACEUTICALS

Dated: March 26, 2008

By: /s/ Michael N. Chang
Name: **Michael N. Chang**
Title: ***President and Chief Executive Officer***

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

Signature	Title	Date
/s/ Michael N. Chang Michael N. Chang	President, Chief Executive Officer and Director (Principal Executive Officer)	March 26, 2008
/s/ John D. Prunty John D. Prunty	Chief Financial Officer (Principal Accounting and Financial Officer)	March 26, 2008
/s/ Anthony E. Altig Anthony E. Altig	Director	March 26, 2008
/s/ Mark Auerbach Mark Auerbach	Director	March 26, 2008
/s/ Joseph Y. Chang Joseph Y. Chang	Director	March 26, 2008
/s/ Martin C. Muenchbach Martin C. Muenchbach	Director	March 26, 2008
/s/ Alain B. Schreiber Alain B. Schreiber	Director	March 26, 2008

Optimer Pharmaceuticals, Inc.
Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of
Optimer Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Optimer Pharmaceuticals, Inc. as of December 31, 2007 and 2006 and the related consolidated statements of operations, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2007. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Optimer Pharmaceuticals, Inc. at December 31, 2007 and 2006, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2007, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 1 to the consolidated financial statements, Optimer Pharmaceuticals, Inc. changed its method of accounting for Share-Based Payments in accordance with Statement of Financial Accounting Standards No. 123 (revised 2004) on January 1, 2006.

/s/ ERNST & YOUNG LLP

San Diego, California
March 25, 2008

Optimer Pharmaceuticals, Inc.
Consolidated Balance Sheets

	December 31, 2007	December 31, 2006
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,191,814	$ 6,122,438
Short-term investments	55,613,785	15,218,860
Research grant and contract receivables	95,184	163,502
Prepaid expenses and other current assets	872,810	1,549,062
Total current assets	59,773,593	23,053,862
Property and equipment, net	705,374	744,564
Other assets	306,573	315,490
Total assets	$ 60,785,540	$ 24,113,916
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 2,602,152	$ 1,753,394
Accrued expenses	4,998,025	3,310,199
Total current liabilities	7,600,177	5,063,593
Deferred rent	281,894	292,384
Commitments and contingencies	—	—
Redeemable convertible preferred stock, $0.001 par value:		
Series B redeemable convertible, no shares and 6,461,439 shares authorized at December 31, 2007 and 2006, respectively; no shares and 4,132,736 shares issued and outstanding at December 31, 2007 and 2006, respectively	—	32,198,929
Series C redeemable convertible, no shares and 1,615,359 shares authorized at December 31, 2007 and 2006, respectively; no shares and 1,538,437 shares outstanding at December 31, 2007and 2006, respectively	—	11,494,052
Series D redeemable convertible, no shares and 3,923,016 shares authorized at December 31, 2007 and 2006, respectively; no shares and 2,861,277 shares issued and outstanding at December 31, 2007 and 2006, respectively	—	21,766,662
Stockholders' equity (deficit):		
Preferred stock, par value $0.001, 10,000,000 shares and no shares authorized at December 31, 2007 and 2006, respectively	—	—
Series A convertible preferred stock, par value $0.001, no shares and 2,307,656 shares authorized at December 31, 2007 and 2006, respectively; no shares and 1,523,051 shares issued and outstanding at December 31, 2007 and 2006, respectively; liquidation preference of $0 and $3,300,000 at December 31, 2007 and 2006	—	1,523
Common stock, $0.001 par value, 75,000,000 shares and 25,384,225 shares authorized at December 31, 2007 and 2006, respectively; 27,903,705 shares and 2,704,476 shares issued and outstanding at December 31, 2007 and 2006, respectively; 46,153 shares held in treasury	27,904	2,704
Treasury stock, at cost; 46,153 shares	(100,000)	(100,000)
Additional paid-in capital	150,681,519	4,997,421
Accumulated other comprehensive loss	(8,396)	(44,971)
Accumulated deficit	(97,697,558)	(51,558,381)
Total stockholders' equity (deficit)	52,903,469	(46,701,704)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 60,785,540	$ 24,113,916

See accompanying notes.

Optimer Pharmaceuticals, Inc.
Consolidated Statements of Operations

	Years Ended December 31,		
	2007	2006	2005
Revenues:			
Research grants	$ 333,610	$ 676,764	$ 1,355,134
Collaborative research agreements	433,555	256,326	791,548
Total revenues	767,165	933,090	2,146,682
Operating expenses:			
Research and development	41,569,067	10,480,924	7,046,625
Marketing	2,048,002	—	—
General and administrative	5,350,800	3,523,221	2,781,966
Total operating expenses	48,967,869	14,004,145	9,828,591
Loss from operations	(48,200,704)	(13,071,055)	(7,681,909)
Interest income and other, net	2,061,527	1,169,160	237,088
Net loss	(46,139,177)	(11,901,895)	(7,444,821)
Accretion to redemption amount of redeemable convertible preferred stock	—	(329,207)	(223,439)
Net loss allocable to common stockholders	$ (46,139,177)	$ (12,231,102)	$ (7,668,260)
Basic and diluted net loss per share attributable to common stockholders	$ (2.12)	$ (4.81)	$ (3.22)
Shares used to compute basic and diluted net loss per share attributable to common stockholders	21,715,332	2,542,893	2,383,435

See accompanying notes.

Optimer Pharmaceuticals, Inc.
Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)

	Redeemable Convertible					
	Series B Preferred Stock		Series C Preferred Stock		Series D Preferred Stock	
	Shares	Amount	Shares	Amount	Shares	Amount
Balance at December 31, 2004	4,132,736	$ 32,175,119	—	$ —	—	$ —
Issuance of common stock upon exercise of options	—	—	—	—	—	—
Issuance of subscribed common stock	—	—	—	—	—	—
Issuance of Series C convertible preferred stock net of issuance costs of $758,921	—	—	1,538,437	11,241,078	—	—
Issuance of Series D convertible preferred stock and common stock warrants net of issuance costs of $827,589	—	—	—	—	2,854,611	21,438,801
Issuance of warrants to acquire Series D convertible preferred stock	—	—	—	—	—	—
Beneficial conversion related to Series D warrants	—	—	—	—	—	—
Accretion of redemption amount for Series B, C and D convertible preferred stock	—	11,905	—	101,189	—	110,345
Compensation expense related to grants of consultant stock options	—	—	—	—	—	—
Comprehensive loss:						
Unrealized loss on short-term investment	—	—	—	—	—	—
Foreign currency translation adjustment	—	—	—	—	—	—
Net loss	—	—	—	—	—	—
Comprehensive loss	—	—	—	—	—	—
Balance at December 31, 2005	4,132,736	32,187,024	1,538,437	11,342,267	2,854,611	21,549,146
Issuance of common stock upon exercise of options	—	—	—	—	—	—
Accretion of redemption amount for Series B, C and D convertible preferred stock	—	11,905	—	151,785	—	165,518
Exercise of Series D warrants	—	—	—	—	6,666	51,998
Compensation expense related to grants of consultant stock options	—	—	—	—	—	—
Employee stock based compensation under FAS123(R)	—	—	—	—	—	—
Repurchase of common stock	—	—	—	—	—	—
Retirement of Series A convertible preferred stock	—	—	—	—	—	—
Comprehensive loss:						
Unrealized loss on short-term investment	—	—	—	—	—	—
Foreign currency translation adjustment	—	—	—	—	—	—
Net loss	—	—	—	—	—	—
Comprehensive loss	—	—	—	—	—	—
Balance at December 31, 2006	4,132,736	32,198,929	1,538,437	11,494,052	2,861,277	21,766,662
Issuance of common stock upon exercise of options	—	—	—	—	—	—
Issuance of common stock during the initial public offerings, net	—	—	—	—	—	—
Issuance of common stock through stock awards	—	—	—	—	—	—
Issuance of common stock pursuant to employee stock purchase plan						
Issuance of common stock during private placement, net						
Conversion of preferred stock to common stock	(4,132,736)	(32,198,929)	(1,538,437)	(11,494,052)	(2,861,277)	(21,766,662)
Issuance of common stock upon exercise of warrants					—	—
Compensation expense related to grants of consultant stock options	—	—	—	—	—	—
Employee stock based compensation under FAS123(R)	—	—	—	—	—	—
Comprehensive loss:						
Unrealized loss on short-term investment	—	—	—	—	—	—
Foreign currency translation adjustment	—	—	—	—	—	—
Net loss	—	—	—	—	—	—
Comprehensive loss	—	—	—	—	—	—
Balance at December 31, 2007	—	$ —	—	$ —	—	$ —

Optimer Pharmaceuticals, Inc.
Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) (Continued)

	Series A Convertible Preferred Stock		Common Stock		Treasury Stock		Stockholders' Equity (Deficit)				
	Shares	Amount	Shares	Amount	Shares	Amount	Capital subscription	Additional paid in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total
Balance at December 31, 2004	1,569,204	$ 1,569	2,345,794	$ 2,346	—	$ —	$ 46,000	$ 3,703,054	$ (4,254)	$ (32,211,665)	$ (28,462,950)
Issuance of common stock upon exercise of options	—	—	13,058	13	—	—	—	7,414	—	—	7,427
Issuance of subscribed common stock	—	—	55,384	55	—	—	(46,000)	45,945	—	—	—
Issuance of Series C convertible preferred stock net of issuance costs of $758,921	—	—	—	—	—	—	—	—	—	—	—
Issuance of Series D convertible preferred stock and common stock warrants net of issuance costs of $827,589	—	—	—	—	—	—	—	742,211	—	—	742,211
Issuance of warrants to acquire Series D convertible preferred stock	—	—	—	—	—	—	—	119,637	—	—	119,637
Beneficial conversion related to Series D warrants	—	—	—	150	—	—	—	119,637	—	—	119,637
Accretion of redemption amount for Series B, C and D convertible preferred stock	—	—	—	—	—	—	—	(223,439)	—	—	(223,439)
Compensation expense related to grants of consultant stock options	—	—	—	—	—	—	—	43,997	—	—	43,997
Comprehensive loss:											
Unrealized loss on short-term investment	—	—	—	—	—	—	—	—	(38,527)	—	(38,527)
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	(6,443)	—	(6,443)
Net loss	—	—	—	—	—	—	—	—	—	(7,444,821)	(7,444,821)
Comprehensive loss	—	—	—	—	—	—	—	—	—	—	(7,489,791)
Balance at December 31, 2005	1,569,204	1,569	2,414,236	2,414	—	—	—	4,558,456	(49,224)	(39,656,486)	(35,143,271)
Issuance of common stock upon exercise of options	—	—	290,240	290	—	—	—	156,096	—	—	156,386
Accretion of redemption amount for Series B, C and D convertible preferred stock	—	—	—	—	—	—	—	(329,208)	—	—	(329,208)
Exercise of Series D warrants	—	—	—	—	—	—	—	—	—	—	—
Compensation expense related to grants of consultant stock options	—	—	—	—	—	—	—	158,850	—	—	158,850
Employee stock based compensation under FAS123(R)	—	—	—	—	—	—	—	553,181	—	—	553,181
Repurchase of common stock	—	—	—	—	(46,153)	(100,000)	—	—	—	—	(100,000)
Retirement of Series A convertible preferred stock	(46,153)	(46)	—	—	—	—	—	(99,954)	—	—	(100,000)
Comprehensive loss:											
Unrealized loss on short-term investment	—	—	—	—	—	—	—	—	(5,872)	—	(5,872)
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	10,125	—	10,125
Net loss	—	—	—	—	—	—	—	—	—	(11,901,895)	(11,901,895)
Comprehensive loss	—	—	—	—	—	—	—	—	—	—	(11,897,642)
Balance at December 31, 2006	1,523,051	1,523	2,704,476	2,704	(46,153)	(100,000)	—	4,997,421	(44,971)	(51,558,381)	(46,701,704)
Issuance of common stock upon exercise of options	—	—	182,382	182	—	—	—	176,365	—	—	176,547
Issuance of common stock during the initial public offerings, net	—	—	7,000,000	7,000	—	—	—	43,612,117	—	—	43,619,117
Issuance of common stock through stock awards	—	—	17,500	18	—	—	—	148,208	—	—	148,226
Issuance of common stock pursuant to employee stock purchase plan	—	—	22,682	23	—	—	—	134,942	—	—	134,965
Issuance of common stock during private placement, net	—	—	4,600,000	4,600	—	—	—	33,550,388	—	—	33,554,988
Conversion of preferred stock to common stock	(1,523,051)	(1,523)	12,246,229	12,247	—	—	—	65,448,919	—	—	65,459,643
Issuance of common stock upon exercise of warrants	—	—	1,130,436	1,130	—	—	—	1,369,137	—	—	1,370,267
Compensation expense related to grants of consultant stock options	—	—	—	—	—	—	—	34,720	—	—	34,720
Employee stock based compensation under FAS123(R)	—	—	—	—	—	—	—	1,209,302	—	—	1,209,302
Comprehensive loss:											
Unrealized loss on short-term investment	—	—	—	—	—	—	—	—	(31,923)	—	(31,923)
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	68,498	—	68,498
Net loss	—	—	—	—	—	—	—	—	—	(46,139,177)	(46,139,177)
Comprehensive loss	—	—	—	—	—	—	—	—	—	—	(46,102,602)
Balance at December 31, 2007	—	$ —	27,903,705	$ 27,904	(46,153)	$ (100,000)	$ —	$ 150,681,519	$ (8,396)	$ (97,697,558)	$ 52,903,469

Optimer Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows

	Years Ended December 31,		
	2007	2006	2005
Operating activities			
Net loss	$ (46,139,177)	$ (11,901,895)	$ (7,444,821)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	285,515	496,211	885,733
Stock based compensation	1,244,022	712,031	43,997
Stock awards	148,226	—	—
Non-cash interest expense related to warrants and beneficial conversion	—	—	239,274
Non-cash compensation related to forgiveness of note receivable from officer	—	262,500	37,500
Gain (loss) on disposal of assets	—	(45,339)	24,906
Deferred revenue	—	—	(14,706)
Deferred rent	(10,490)	12,970	35,637
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	676,252	(1,449,189)	6,612
Research grant and contract receivables	68,318	466,626	(525,775)
Other assets	8,917	(2,894)	111,943
Accounts payable and accrued expenses	2,536,584	2,943,357	1,197,221
Net cash used in operating activities	(41,181,833)	(8,505,622)	(5,402,479)
Investing activities			
Purchases of short-term investments	(86,993,067)	(10,478,237)	(9,975,025)
Sales or maturity of short-term investments	46,610,000	5,190,000	—
Purchase of property and equipment	(246,326)	(46,173)	(44,743)
Net cash used in investing activities	(40,629,393)	(5,334,410)	(10,019,768)
Financing activities			
Proceeds from sale of preferred stock, net of issuance costs	—	—	33,422,090
Proceeds from sale of common stock	77,485,617	156,386	7,427
Proceeds from exercise of Series D warrants	1,370,267	51,998	—
Repurchase of common stock	—	(100,000)	—
Repurchase of Series A preferred stock	—	(100,000)	—
Repayments of proceeds from capital leases	—	—	(9,369)
Net cash provided by financing activities	78,855,884	8,384	33,420,148
Effect of exchange rate changes on cash and cash equivalents	24,718	10,127	(6,443)
Net increase (decrease) in cash and cash equivalents	(2,930,624)	(13,821,521)	17,991,458
Cash and cash equivalents at beginning of year	6,122,438	19,943,959	1,952,501
Cash and cash equivalents at end of year	$ 3,191,814	$ 6,122,438	$ 19,943,959
Supplemental disclosure of cash flow information:			
Interest paid	$ —	$ —	$ 7,501
Conversion of redeemable convertible preferred stock to common stock	65,461,166	—	—

See accompanying notes.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Summary of Significant Accounting Policies

Optimer Pharmaceuticals, Inc. ("Optimer" or the "Company") was incorporated in Delaware on November 18, 1998 and has three subsidiaries. Optimer Biotechnology, Inc. is a wholly owned subsidiary of the Company and is incorporated in Taiwan while Optimer Singapore PTE LTD ("Optimer Singapore") and Optimer Asia PTE LTD are incorporated in Singapore and are wholly owned subsidiaries of Optimer Biotechnology, Inc. During the year ended December 31, 2006, the Company had ceased operations of Optimer Asia PTE LTD and Optimer Singapore, respectively, neither of which had a material impact on the consolidated financial statements.

Optimer is a biopharmaceutical company focused on discovering, developing and commercializing anti-infective products. The Company currently has two anti-infective product candidates, OPT-80 for the treatment of *Clostridium difficile*-infections, and Prulifloxacin, for the treatment of infectious diarrhea in travelers.

Stock Split

In December 2006 and January 2007, the Company's board of directors and stockholders authorized a 1-for-2.1667 reverse stock split for all outstanding preferred and common shares. All share information has been retroactively restated to reflect the reverse stock split.

Principles of Consolidation

The consolidated financial statements include all the accounts of the Company and its three wholly owned subsidiaries in Asia. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Cash, Cash Equivalents and Short-Term Investments

Investments with original maturities of less than 90 days at the date of purchase are considered to be cash equivalents. All other investments are classified as short-term investments which are deemed by management to be available-for-sale and are reported at fair value with net unrealized gains or losses reported within other comprehensive loss in the consolidated statement of redeemable convertible preferred stock and stockholders' equity (deficit). Realized gains and losses, and declines in value judged to be other than temporary, are included in investment income or interest expense. The cost of securities sold is computed using the specific identification method.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a significant concentration of credit risk consist primarily of cash and cash equivalents and short-term investments. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. However, management believes the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. Additionally, the Company has established guidelines regarding diversification of its investments and their maturities, which are designed to maintain safety and liquidity.

Property and Equipment

Property and equipment, including leasehold improvements, are stated at cost. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, generally five years. Leasehold improvements are amortized over the shorter of their useful lives or the terms of the related leases.

Deferred Rent

Rent expense is recorded on a straight-line basis over the term of the lease. The difference between rent expense accrued and amounts paid under the lease agreement is recorded as deferred rent in the accompanying consolidated balance sheets.

Redeemable Convertible Preferred Stock

In connection with the closing of the Company's initial public offering in February 2007, all shares of redeemable convertible preferred stock were converted to common stock. Prior to the initial public offering, the carrying value of redeemable convertible preferred stock was increased by periodic accretions so that the carrying amount would equal the redemption value at the redemption date. These accretions were effected through charges against additional paid in capital.

Foreign Currency Translation

The financial statements of foreign subsidiaries having the U.S. dollar as the functional currency, with certain transactions denominated in a local currency, are remeasured into U.S. dollars at their historical rates. The remeasurement of local currency amounts into U.S. dollars creates translation adjustments that are included in net loss. Transaction and translation gains or losses were not material to the financial statements for any periods presented.

Fair Value of Financial Instruments

The carrying amount of cash and cash equivalents, short-term investments and accounts payable and accrued liabilities are considered to be representative of their respective fair values because of the short-term nature of those instruments. The fair value of available-for-sale securities is based upon market prices quoted on the last day of the fiscal period.

Impairment of Long-Lived Assets

In accordance with Statement of Financial Accounting Standards ("SFAS") No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, long-lived assets, such as property and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset. Assets to be disposed of would be separately presented in the balance sheet and reported at the lower of the carrying amount or the fair value less costs to sell, and are no longer depreciated. The assets and liabilities of a disposed group classified as held for sale would be presented separately in the appropriate asset and liability sections of the balance sheet. Although the Company has accumulated losses since inception, the Company believes the future cash flows to be received from the long-lived assets will exceed the assets' carrying value and, accordingly, the Company has not recognized any impairment losses through December 31, 2007.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. The Company provides a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax assets will be realized.

Revenue Recognition

The Company's collaboration agreements contain multiple elements, including non-refundable upfront fees, payments for reimbursement of third-party research costs, payments for ongoing research, payments associated with achieving specific development milestones and royalties based on specified percentages of net product sales, if any. The Company applies the revenue recognition criteria outlined in Staff Accounting Bulletin ("SAB") No. 104, *Revenue Recognition* and Emerging Issues Task Force ("EITF") Issue 00-21, *Revenue Arrangements with Multiple Deliverables* ("EITF 00-21"). In applying these revenue recognition criteria, the Company considers a variety of factors in determining the appropriate method of revenue recognition under these arrangements, such as whether the elements are separable, whether there are determinable fair values and whether there is a unique earnings process associated with each element of a contract.

Cash received in advance of services being performed is recorded as deferred revenue and recognized as revenue as services are performed over the applicable term of the agreement.

When a payment is specifically tied to a separate earnings process, revenues are recognized when the specific performance obligation associated with the payment is completed. Performance obligations typically consist of significant and substantive milestones pursuant to the related agreement. Revenues from milestone payments may be considered separable from funding for research services because of the uncertainty surrounding the achievement of milestones for products in early stages of development. Accordingly, these payments are allowed to be recognized as revenue if and when the performance milestone is achieved if they represent a separate earnings process as described in EITF 00-21.

In connection with certain research collaboration agreements, revenues are recognized from non-refundable upfront fees, which the Company does not believe are specifically tied to a separate earnings process, ratably over the term of the agreement. Research fees are recognized as revenue as the related research activities are performed.

Revenues derived from reimbursement of direct out-of-pocket expenses for research costs associated with grants are recorded in compliance with EITF Issue 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent*, and EITF Issue 01-14, *Income Statement Characterization of Reimbursements Received for "Out-of-Pocket" Expenses Incurred.* According to the criteria established by these EITF Issues, in transactions where the Company acts as a principal, with discretion to choose suppliers, bear credit risk and perform part of the services required in the transaction, the Company records revenue for the gross amount of the reimbursement. The costs associated with these reimbursements are reflected as a component of research and development expense in the consolidated statements of operations.

None of the payments that the Company has received from collaborators to date, whether recognized as revenue or deferred, are refundable even if the related program is not successful.

Research and Development Expenses

The Company accounts for research and development costs in accordance with SFAS No. 2, *Accounting for Research and Development Costs* ("SFAS 2"). SFAS 2 specifies that research and development costs should be charged to expense until technological feasibility has been established for the product. Once technological feasibility is established, all product costs should be capitalized until the product is available for general release to customers. The Company has determined that technological feasibility for its product candidates will be reached when the requisite regulatory approvals are obtained to make the product available for sale, or approval of the new drug application ("NDA") for such product. The Company's research and development expenses consist primarily of license fees, salaries and related employee benefits, costs associated with clinical trials managed by the Company's contract research organizations, or CROs, and costs associated with non-clinical activities and regulatory approvals. The Company uses external service providers and vendors to conduct clinical trials, to manufacture supplies of product candidates to be used in clinical trials and to provide various other research and development-related products and services.

When nonrefundable payments for goods or services to be received in the future for use in research and development activities are made, the Company applies the criteria outlined in EITF issue No. 07-3 (" EITF 07-3"),

Accounting for Non-Refundable Advance Payments for Goods or Services to be Used in Future Research and Development Activities. In accordance with EITF 07-3, these types of payments are deferred and capitalized. The capitalized amounts are expensed when the related goods are delivered or the services are performed.

Stock-Based Compensation

Effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards, ("SFAS"), No. 123(R), *Share-Based Payment*, which revises SFAS No. 123, *Accounting for Stock-Based Compensation* and supersedes Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*. SFAS No. 123(R) requires that share-based payment transactions with employees be recognized in the financial statements based on their fair value and recognized as compensation expense over the vesting period. The Company used the modified prospective-transition-method when it adopted SFAS 123(R), and accordingly, the Company did not restate its results of operations for the prior periods. Compensation expense of $1.2 million and $0.7 million was recognized in the years ended December 31, 2007 and 2006, respectively, for all awards granted on or after December 31, 2005 as well as for the unvested portion of awards granted before December 31, 2005.

Stock-based compensation expense is estimated as of the grant date based on the fair value of the award and is recognized as expense over the requisite service period, which generally represents the vesting period. The Company estimates the fair value of its stock options using the Black-Scholes option-pricing model and the fair value of its stock awards based on the quoted market price of its common stock.

Estimating the fair value for stock options requires judgment, including estimating stock-price volatility, expected term, expected dividends and risk-free interest rates. The expected volatility rates are based on the historical fluctuation in the stock price since inception. The average expected term is calculated using SAB No. 107, "*Simplified Method for Estimating the Expected Term*". Expected dividends are estimated based on the Company's dividend history as well as the Company's current projections. The risk-free interest rate for periods approximating the expected terms of the options is based on the U.S. Treasury yield curve in effect at the time of grant. These assumptions are updated on an annual basis or sooner if there is a significant change in circumstances that could affect these assumptions.

Equity instruments issued to non-employees are recorded at their fair value as determined in accordance with SFAS No. 123(R) and EITF 96-18, *Accounting for Equity Instruments That are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods and Services*, and are periodically revalued as the equity instruments vest and are recognized as expense over the related service period.

Comprehensive Income (Loss)

The Company has applied SFAS No. 130, *Reporting Comprehensive Income*, which requires that all components of comprehensive income (loss), including net income (loss), be reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income (loss) and other comprehensive income (loss), including foreign currency translation adjustments and unrealized gains and losses on investments, is required to be reported, net of their related tax effect, to arrive at comprehensive income (loss).

Net Loss Per Share Attributable to Common Stockholders

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of common stock equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, convertible preferred stock, stock options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share attributable to common stockholders when their effect is dilutive.

	Years Ended December 31,		
	2007	2006	2005
Historical			
Numerator:			
Net loss attributable to common stockholders	$ (46,139,177)	$ (12,231,102)	$ (7,668,260)
Denominator:			
Weighted average common shares outstanding	21,715,332	2,542,893	2,383,435
Net loss attributable to common stockholders per share — basic and diluted	$ (2.12)	$ (4.81)	$ (3.22)
Historical outstanding anti-dilutive securities not included in diluted net loss per share calculation			
Preferred stock (as converted)	—	12,223,548	12,261,701
Preferred stock warrants (as converted)	—	22,705	30,705
Common stock options	1,615,317	1,496,945	1,455,022
Common stock warrants	13,845	1,144,604	1,155,681
	1,629,162	14,887,802	14,903,109

Recent Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board, or FASB, issued FASB Statement No. 157, "*Fair Value Measurements*" ("SFAS 157"), which defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 applies to other accounting pronouncements that require or permit fair value measurements. The new guidance is effective for financial statements issued for fiscal years beginning after November 15, 2007, and for interim periods within those fiscal years. The Company is currently evaluating the impact of SFAS 157, but does not believe the adoption of this standard will have a material impact on its consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, "*The Fair Value Option for Financial Assets and Liabilities*" ("SFAS 159"). SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. SFAS 159 will be effective for the Company's fiscal year beginning after November 15, 2007. Early adoption is permitted. The Company is currently evaluating the impact of SFAS 159, but does not believe the adoption of this standard will have a material impact on its financial position, cash flows, and results of operations.

In July 2007, the FASB released EITF Issue 07-3, *"Accounting for Nonrefundable Advance Payments for Goods or Services to be used in Future Research and Development Activities"* ("EITF 07-3"). In accordance with EITF 07-3, nonrefundable advance payments for goods or services to be received in the future for use in research and development activities should be deferred and capitalized. The capitalized amounts should be expensed as the related goods are delivered or the services are performed. EITF 07-3 is effective for new contracts entered into during fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. The Company's current accounting treatment is consistent with EITF 07-3 and as such this EITF is not expected to have an impact on its financial position, cash flows, and results of operations.

In December 2007, the FASB issued Statement of Financial Accounting Standards, or SFAS No. 160, *"Noncontrolling Interests in Consolidated Financial Statements — An Amendment of ARB No. 51"* ("SFAS 160"). SFAS 160 requires the recognition of a noncontrolling interest, sometimes called minority interest, as equity in the consolidated financial statements and separate from the parent's equity. The amount of net income attributable to the noncontrolling interest will be included in consolidated net income on the face of the income statement. SFAS 160 clarifies that changes in a parent's ownership interest in a subsidiary that do not result in deconsolidation are equity transactions if the parent retains its controlling financial interest. In addition, this statement requires that a parent recognize a gain or loss in net income when a subsidiary is deconsolidated. Such gain or loss will be measured using the fair value of the noncontrolling equity investment on the deconsolidation date. SFAS 160 also includes expanded disclosure requirements regarding the interests of the parent and its noncontrolling interest. SFAS 160 is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. Earlier adoption is prohibited. The Company has not determined the impact, if any, in adopting this standard may have on its financial position, cash flows, and results of operations.

2. Short-Term Investments

Investment securities are classified as available-for-sale and include high grade auction rate securities, or ARS. The ARS have either a stated or a perpetual maturity that is structured with short-term holding periods. At the end of each holding period, a new auction is held to determine the rate or dividend for the next holding period. The Company can sell or continue to hold securities at par at each auction. In order to sell ARS, the auction needs to be successful whereby demand in the marketplace exceeds the supply. The length of each holding period is determined at the original issuance of the ARS. Typically, ARS holding periods range from 7 to 63 days, but occasionally the Company invests in ARS with longer reset dates. As of December 31, 2007, the Company held $14.2 million of ARS with stated maturity dates ranging from 2022 to 2037 and reset dates primarily less than 30 days.

The following is a summary of the Company's investment securities, all of which are classified as available-for-sale. Determination of estimated fair value is based upon quoted market prices.

	December 31, 2007			
	Gross Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Market Value
Certificates of deposits	$ 4,802,335	$ 1,515	$ (2,234)	$ 4,801,616
Commercial paper	7,464,847	259	(650)	7,464,456
Corporate debt securities	20,856,371	9,378	(43,527)	20,822,222
Foreign debt securities	3,323,878	6,947	(3,479)	3,327,346
U.S. securities and other government obligations	3,500,647	5,118	—	3,505,765
Taxable auction securities	14,200,000	—	—	14,200,000
Other securities	1,498,251	—	(5,871)	1,492,380
	$ 55,646,329	$ 23,217	$ (55,761)	$ 55,613,785

	December 31, 2006			
	Gross Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Market Value
Government obligations	$ 15,263,259	$ —	$ (44,399)	$ 15,218,860

Investments in net unrealized loss positions as of December 31, 2007 are as follows:

	Number of Investments	Less Than 12 Months of Temporary Impairment		Greater Than 12 Months of Temporary Impairment		Total Temporary Impairment	
		Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Commercial paper	3	$ 4,475,505	$ (650)	$ —	$ —	$ 4,475,505	$ (650)
Certificate of deposit	3	3,399,598	(2,234)	—	—	3,399,598	(2,234)
Corporate debt securities	11	10,617,187	(43,527)	—	—	10,617,187	(43,527)
Foreign debt securities	3	2,305,696	(3,479)	—	—	2,305,696	(3,479)
Other Securities	1	1,492,380	(5,871)	—	—	1,492,380	(5,871)
	21	$ 22,290,366	$ (55,761)	$ —	$ —	$ 22,290,366	$ (55,761)

The amortized cost and estimated fair value of securities available-for-sale at December 31, 2007, by contractual maturity, are as follows:

	Amortized Cost	Estimated Fair Value
Due in one year or less	$ 36,953,863	$ 36,931,288
Due after one year through two years	18,692,466	18,682,497
	$ 55,646,329	$ 55,613,785

The Company believes that the decline in value is temporary and primarily related to the change in market interest rates since purchase. The Company anticipates full recovery of amortized cost with respect to these securities at maturity or sooner in the event of a change in the market interest rate environment.

3. Property and Equipment

Property and equipment is stated at cost and consists of the following:

	December 31,	
	2007	2006
Equipment	$ 3,016,275	$ 3,033,589
Furniture and fixtures	279,923	292,688
Leasehold improvements	1,368,179	1,268,987
Computer equipment and software	224,802	197,793
	4,889,179	4,793,057
Less accumulated depreciation and amortization	(4,183,805)	(4,048,493)
	$ 705,374	$ 744,564

Depreciation of property and equipment is computed using the straight-line method over the estimated useful lives of the assets, which typically is five years. Leasehold improvements and assets acquired under capital leases are amortized over their estimated useful life or the related lease term, whichever is shorter. The depreciation of equipment under capital leases is included in depreciation expense. As of December 31, 2007 and 2006, the Company did not have any capital leases.

4. Note Receivable from Officer

Note receivable from officer of $262,500 as of December 31, 2005, represents an uncollateralized loan to an officer for housing and relocation assistance with an original balance of $300,000. With the renewal of the officer's employment agreement in June 2005, the board of directors agreed to forgive the loan ratably over four years subject to the officer being an employee of the Company. In November 2006, the loan and the related interest were forgiven.

5. Accrued Expenses

Accrued expenses consisted of the following:

	December 31, 2007	December 31, 2006
Accrued preclinical and clinical expenses	$ 3,726,891	$ 2,566,433
Accrued research services	172,754	132,367
Accrued legal fees	64,007	232,280
Accrued salaries, wages and benefits	980,448	206,469
Other accrued liabilities	53,925	172,650
	$ 4,998,025	$ 3,310,199

6. Revenue and Other Collaborative Agreements

Revenues from Research Grants

Since 2003, the Company has received Small Business Innovative Research ("SBIR") grants from U.S. government agencies totaling $3,333,213, including three SBIR grants received in 2005 totaling $1,454,827 and two SBIR grants received in 2006 and 2007 totaling $1,578,386. The 2007 grant is renewable each year until August 2010 to a maximum of $3 million over a three year funding period. The purpose of the grants was to support research on certain antibiotic and osteoarthritis drug candidates being developed by the Company and to conduct supplementary studies to the ongoing OPT-80 clinical trials. For the years ended December 31, 2007, 2006 and 2005, the Company recognized revenues related to these grants of $338,735, $493,960 and $1,097,024, respectively. Through 2007, the Company recognized revenues of $2,188,932 related to these grants. As of December 31, 2007, $1,095,647 of revenue is remaining to be recognized under the grants.

In 2003, Optimer received a grant in the amount of $721,150 from the Philip Morris External Research Program ("Philip Morris") to support development of a carbohydrate-based cancer immunotherapy. The research grant was for a three-year research period and was subject to renewal annually by Philip Morris. Optimer retained all rights to the data and novel glycosylation methods developed pursuant to research funded by the grant. For the years ended December 31, 2007, 2006 and 2005, the Company recognized revenue of $0, $182,804 and $239,416 respectively, under the grant.

Revenues from Collaborative Research Agreements

For the years ended December 31, 2007, 2006 and 2005, the Company recognized revenues of $433,555, $256,326 and $791,548, respectively, under collaborative research agreements with large pharmaceutical companies and research institutions.

In May 2003, Optimer entered into a manufacturing supply agreement with the Sloan-Kettering Institute for Cancer Research ("SKI") to manufacture certain conjugates for SKI in support of SKI's on-going U.S. Phase 2 clinical trials for a product candidate to treat breast cancer. According to the terms of the agreement, Optimer was eligible to receive up to $1,000,000 over the term of the agreement, if the Company met the manufacturing performance obligations contained in the agreement. Through 2004, the Company received a non-refundable advance payment of $250,000 under the agreement, all of which has been recognized ratably over the agreement term, as research contract revenue, including $14,705 and $172,795 in 2005 and 2004, respectively. In 2004, the Company informed SKI that it intended to terminate the agreement after completion of the first $250,000 milestone payment under the contract. In 2005, the Company achieved the first milestone and accordingly recognized $250,000 of research contract revenue and terminated the agreement.

In June 2005, Optimer entered into a binding letter agreement establishing a development and license agreement with a pharmaceutical company to develop one or more pharmaceutical products using Optimer's proprietary carbohydrate synthesis technology. Optimer was reimbursed at an agreed upon rate for research services performed under the contract. The pharmaceutical company was responsible, at its own expense, for carrying out pre-clinical tests, animal tests, human clinical trials, marketing and commercializing any product candidates pursued

under the terms of the agreement. The agreement included milestone and royalty payments to Optimer assuming the successful development and commercialization of a product candidate. In November 2006, the collaboration was terminated. Through December 31, 2006, Optimer recognized $678,168 of research revenue under the terms of the agreement.

Other Collaborative Agreements

In April 2005, the Company entered into a collaboration agreement with Par to develop and commercialize OPT-80. The Company granted to Par an exclusive royalty bearing license, with the right to sublicense, promote, market, distribute and sell OPT-80 in a territory composed of the United States, Canada and Puerto Rico, with an option to extend the territory to include Israel. The Company retained all other rights to OPT-80 in the rest of the world. At the time of execution of this collaboration agreement, Par also purchased $12.0 million of the Company's Series C Preferred Stock.

In January 2007, the Company entered into a prospective buy-back agreement with Par which provided us with an option to terminate the collaboration and repurchase the rights to develop and commercialize OPT-80 in North America and Israel.

In February 2007, the Company elected to terminate the collaboration agreement with Par, exercised its rights under the prospective buy-back agreement to repurchase Par's right to develop and commercialize OPT-80 in North America and Israel. The Company now holds worldwide rights to OPT-80. In connection with the exercise of the rights under the prospective buy-back agreement, the Company paid Par a one-time $20.0 million termination fee and $1.9 million for OPT-80 clinical supply material and active pharmaceutical ingredient in 2007. The Company is also obligated to pay Par a one-time $5.0 million milestone payment, a potential $3.0 million prepayment to Biocon, subject to future set-offs following the assignment, if any, by Par to the Company of its supply agreement with Biocon, a 5% royalty on net sales by the Company, its affiliates or its licensees of OPT-80 in North America and Israel, and a 1.5% royalty on net sales by the Company or its affiliates of OPT-80 in the rest of the world. The one-time $5.0 million milestone payment shall be paid after the earliest to occur of (i) the successful completion by the Company of its pivotal Phase 3 trial for OPT-80, (ii) the Company's grant to a third party of the rights to OPT-80 or (iii) the submission to the FDA of an NDA for OPT-80. In addition, in the event the Company licenses its right to market OPT-80 in the rest of the world, the Company will be required to pay Par a 6.25% royalty on net revenues received by it related to OPT-80. The Company is obligated to pay each of these royalties, if any, on a country-by-country basis for seven years commencing on the applicable commercial launch in each such country.

In March 2006, the Company entered into a collaborative research and development and license agreement with Cempra Pharmaceuticals, Inc. ("Cempra"). The Company granted to Cempra an exclusive worldwide license, except in ASEAN countries, with the right to sublicense, the Company's patent and know-how related to the Company's macrolide and ketolide antibacterial program. As partial consideration for granting Cempra the licenses, the Company obtained common stock of Cempra and the Company assigned no value to such shares. The Company will receive milestone payments as product candidates are developed and/or co-developed by Cempra, in addition to milestone payments based on certain sublicense revenue. The aggregate potential amount of such milestone payments is not capped and, based in part on the number of products developed under the agreement, may exceed $24.5 million. The Company will also receive royalty payments based on a percentage of net sales of licensed products. The Company will receive milestone payments as product candidates are developed and/or co-developed by Cempra and will be triggered upon the completion of certain clinical development milestones and in certain instances, regulatory approval of products. The Company will also receive royalty payments based on a percentage of net sales of licensed products. In consideration of the foregoing, Cempra will receive milestone payments from the Company in the amount of $1.0 million for each of the first two products the Company develops which receive regulatory approval in ASEAN countries, as well as royalty payments on the net sales of such products. The research term of this agreement continues until the earlier of the Company's completion of all research activities set forth in the work plan under the agreement, or March 2008. Subject to certain exceptions, on a country-by-country basis, the general terms of this agreement continue until the later of: (i) the expiration of the last to expire patent rights of a covered product in the applicable country or (ii) ten years from the first commercial sale of a covered product in the applicable country. Either party may terminate the agreement in the event of a material breach by the other party, subject to prior notice and the opportunity to cure. Either party may also terminate the agreement for

any reason upon 30 days' prior written notice provided that all licenses granted by the terminating party to the non-terminating party shall survive upon the express election of the non-terminating party.

In June 2004, the Company entered into a license agreement with Nippon Shinyaku, Co., Ltd. ("Nippon Shinyaku"). Under the terms of the agreement, the Company acquired the non-exclusive right to import and purchase Prulifloxacin, and the exclusive right (with the right to sublicense), within the United States, to develop, make, use, offer to sell, sell and license products suitable for consumption by humans containing Prulifloxacin. Under this agreement, the Company paid Nippon Shinyaku an up-front fee in the amount of $1.0 million and will be required to make one future milestone payment in the amount of $1.0 million upon filing, if any, its first NDA in the United States. Under the agreement, the Company pays Nippon Shinyaku for certain materials. If Nippon Shinyaku is unable to supply the Company with the contracted amount of Prulifloxacin, then Nippon Shinyaku will grant to the Company a non-exclusive, worldwide license to make or have made Prulifloxacin, in which event the Company will owe Nippon Shinyaku a royalty based on the amount of net sales of Prulifloxacin generated by the Company and the Company's subsidiaries. Additionally, the Company will owe Nippon Shinyaku certain royalties based on the amount of net sales of Prulifloxacin less the amount of Prulifloxacin we buy from Nippon Shinyaku. Either party may terminate the agreement 60 days after giving notice of a material breach which remains uncured 60 days after written notice. If not terminated earlier, the agreement will terminate upon the later of ten years from the date of the first commercial sale of Prulifloxacin in the United States or until the date on which the last valid patent claim relating to Prulifloxacin expires in the United States.

In July 2002, the Company entered into a license agreement with SKI, to acquire, together with certain nonexclusive licenses, exclusive, worldwide licensing and sublicensing rights to certain patented and patent-pending carbohydrate-based cancer immunotherapies. As partial consideration for the licensing rights, the Company paid to SKI a one-time fee consisting of both cash and 55,383 shares of its common stock. Under the agreement, which was amended in June 2005, the Company owes SKI milestone payments in the following amounts for each licensed product: (i) $500,000 upon the commencement of Phase 3 clinical studies, (ii) $750,000 upon the filing of the first NDA, (iii) $1.5 million upon marketing approval in the United States and (iv) $1.0 million upon marketing approval in each and any of Japan, and certain European countries, but only to the extent that the Company, and not a sublicensee, achieves such milestones. The Company also owes SKI royalties based on net sales generated from the licensed products and income the Company sources from its sublicensing activities, which royalty payments are credited against a minimum annual royalty payment the Company owes to SKI during the term of the agreement. The term of the agreement continues until the later of July 31, 2017, or the expiration of the last to expire of the patents licensed under this agreement, unless the agreement is earlier terminated. The agreement can be terminated by SKI for a variety of reasons, including (i) upon 60 days' notice in the event the Company fails to meet a development milestone specified in the agreement or (ii) upon 30 days' notice, in the event the Company fails to pay any licensing fees, royalties or patent expenses due under the agreement within 30 days of the due date and thereafter fail to pay such deficit in-full within the 30-day notice period.

In July 1999, the Company acquired exclusive, worldwide rights to OPopS technology from the Scripps Research Institute ("TSRI"). This agreement includes the license to the Company of patents, patent applications and copyrights related to OPopS technology. The Company also acquired, pursuant to three separate license agreements with TSRI, exclusive, worldwide rights to over 20 TSRI patents and patent applications related to other potential drug compounds and technologies, including HIV/FIV protease inhibitors, aminoglycoside antibiotics, polysialytransferase, selectin inhibitors, nucleic acid binders, carbohydrate mimetics and osteoarthritis. Under the four agreements, the Company paid TSRI license fees consisting of an aggregate of 239,996 shares of its common stock with a deemed aggregate fair market value of $46,400, as determined on the dates of each such payment. Additionally, under each agreement, the Company owes TSRI royalties based on net sales by the Company, its affiliates and sublicensees of the covered products and royalties based on revenue the Company generates from sublicenses granted pursuant to the agreements. For the first licensed product under each of the four agreements, the Company will also owe TSRI payments upon achievement of certain milestones. In three of the four TSRI agreements, the milestones are the initiation of a Phase 2 trial or its foreign equivalent, the filing of an NDA or its foreign equivalent and government marketing and distribution approval. In the remaining TSRI agreement, the milestones are the successful completion of a Phase 3 trial or its foreign equivalent, the filing of an NDA or its foreign equivalent and government marketing and distribution approval. The aggregate potential amount of milestone payments the Company may be required to pay TSRI under all four TSRI agreements is approximately $14.0 million. Each TSRI agreement terminates in part as follows: (i) with respect to each product which utilizes

patent rights licensed under the agreement, on a country-by-country basis concurrently with the expiration of the last to expire of the applicable patent rights, (ii) with respect to each product which utilizes technology licensed under the agreement but which does not utilize patent rights also licensed thereunder, 15 years after the date of the first commercial sale of the product in each country and (iii) with respect to software licensed under the 1999 OPopS agreement, 75 years after the date the applicable copyright is filed in the United States.

7. Commitments

Leases

The Company leases office and research facilities under operating lease agreements that extend through November 2011. The Company has recorded deferred rent of $281,894 and $292,384 as of December 31, 2007 and 2006, respectively, in conjunction with one of the lease agreements.

At December 31, 2007, annual minimum rental payments due under the Company's operating leases are as follows:

Years ending December 31,	
2008	$ 783,950
2009	793,849
2010	683,255
2011	626,317
Total minimum lease payments	$2,887,371

Rent expense was $768,854, $837,551 and $817,813, for the years ended December 31, 2007, 2006, and 2005, respectively.

Contract Research Organization Purchase Orders

The Company has contracted with a contract research organization ("CRO"), whereby the CRO will provide clinical research services to the Company for the OPT-80 Phase 3 clinical trials and Prulifloxacin Phase 3 clinical trials. At December 31, 2007, the Company had issued purchase orders totaling $33,954,753 for these services, $20,388,054 and $9,757,661 of which were issued in 2006 and 2007, respectively. As of December 31, 2007, the Company had paid $12,533,810 related to these purchase orders. The Company can terminate the service agreement at any time upon 60 days' prior written notice to the CRO.

8. Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)

Private Placement

On October 30, 2007, the Company completed a private placement in which it raised gross proceeds of approximately $35.9 million through the sale, at a price of $7.80 per share, of 4.6 million shares of its common stock. Pursuant to the terms of the private placement, the Company filed a registration statement with the SEC to register for resale the shares of common stock sold in the private placement. This registration statement became effective December 19, 2007.

Initial Public Offering

On February 14, 2007, the Company completed the initial public offering of 7.0 million shares of common stock at $7.00 per share in connection with the closing of our initial public offering resulting in aggregate proceeds of approximately $43.6 million, net of underwriting discounts and commissions and offering expenses.

Treasury Stock

In September 2006, the Company reacquired 46,153 shares of previously issued common stock at $2.17 per share from a former executive officer. The shares were recorded as treasury stock at their cost. The 46,153 shares of common stock remain in treasury as of December 31, 2007.

Warrants

In connection with the Company's building lease agreement signed in 2000, the Company issued a warrant to purchase 13,845 shares of common stock at a purchase price of $10.83. The estimated fair value of the warrant at the date of grant was not material using the Black-Scholes valuation model. As of December 31, 2007, no shares had been issued pursuant to this warrant. This warrant expired on February 9, 2008.

Equity Compensation Plans

Stock Options

In November 1998, the Company adopted the 1998 Stock Plan (the "1998 Plan"). Upon the completion of the Company's initial public offering in February 2007, the 1998 Plan was terminated and no additional grants will be issued from this plan. In December 2006, the Company's board of directors approved the 2006 Equity Incentive Plan (the "2006 Plan"). The 2006 Plan provides for the grant of incentive stock options, within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended, to the Company's employees and any parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to the Company's employees, directors and consultants and any parent and subsidiary corporations' employees and consultants. The Company initially reserved a total of 2,000,000 shares of its common stock for issuance pursuant to the 2006 Plan. In addition, the 2006 Plan provides for annual increases in the number of shares available for issuance thereunder on the first day of each fiscal year, beginning with the Company's 2008 fiscal year, equal to the lesser of (i) 5% of the outstanding shares of the Company's common stock on the last day of the immediately preceding fiscal year; (ii) 750,000 shares; or (iii) such other amount as the board of directors may determine. Pursuant to this provision, 750,000 additional shares of the Company's common stock were reserved for issuance under the 2006 Plan on January 1, 2008. Under the 2006 Plan, the exercise price of options granted must at least be equal to the fair market value of the Company's common stock on the date of grant. The term of an incentive stock option may not exceed ten years from the date of grant (five years for a 10% stockholder). Options generally vest over a period of four years. The 2006 Plan is administered by the compensation committee of the Company's board of directors.

Following is a summary of stock option activity:

	Options	Weighted-Average Exercise Price
Balance as of December 31, 2004	1,148,631	$ 0.69
Granted	411,244	$ 1.08
Exercised	(13,057)	$ 0.56
Canceled	(91,796)	$ 0.98
Balance as of December 31, 2005	1,455,022	$ 0.78
Granted	367,517	$ 2.08
Exercised	(279,163)	$ 0.52
Canceled	(46,431)	$ 0.71
Balance as of December 31, 2006	1,496,945	$ 1.17
Granted	310,353	$ 8.84
Exercised	(182,385)	$ 0.96
Canceled	(9,596)	$ 3.70
Balance as of December 31, 2007	1,615,317	$ 2.65

The aggregate intrinsic value of options exercised during the year ended December 31, 2007 was approximately $1,070,930. The aggregate intrinsic value of options outstanding and options exercisable as of December 31, 2007 was approximately $7,673,553 and $5,759,375, respectively.

The following table summarizes information concerning outstanding and exercisable stock options as of December 31, 2007:

	December 31, 2007				
	Options Outstanding			Options Exercisable	
Exercise Price	Number of Shares Subject to Options Outstanding	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price	Number of Shares Exercisable	Weighted Average Exercise Price
$0.22	58,460	3.0	$ 0.22	58,460	$ 0.22
$0.65	378,254	4.0	$ 0.65	378,254	$ 0.65
$1.08	543,397	7.2	$ 1.08	395,389	$ 1.08
$2.17	343,456	8.6	$ 2.17	128,598	$ 2.17
$7.10-$10.00	291,750	9.4	$ 9.21	—	$ —
$0.22-$10.00	1,615,317	7.0	$ 2.65	960,701	$ 1.01

As of December 31, 2007, 1,615,317 options were outstanding at exercise prices ranging from $0.22 to $10.00 per share. The weighted average remaining contractual life of options outstanding at December 31, 2007 was 7.0 years with a weighted average exercise price of $2.65 per share. Of the options outstanding, options to purchase up to 960,701 shares were vested as of December 31, 2007, with a weighted average remaining contractual life of 5.8 years and a weighted average exercise price of $1.01 per share, while options to purchase up to 654,616 shares were unvested.

Share-Based Compensation

Effective January 1, 2006, the Company adopted the provisions of SFAS No. 123(R) using the modified prospective-transition-method and therefore, prior period results will not be restated. SFAS No. 123(R) supersedes Accounting Principles Board ("APB") Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB Opinion 25"), and related interpretations, and revises guidance in SFAS No. 123, *Accounting for Stock-Based Compensation* ("SFAS 123"). Under this transition method, the compensation costs related to all equity instruments granted prior to, but not yet vested as of, the adoption date of SFAS 123(R) are recognized based on the grant-date fair value which is estimated in accordance with the original provisions of SFAS 123. Compensation costs related to all equity instruments granted after January 1, 2006 are recognized at the grant-date fair value of the awards in accordance with the provisions of SFAS 123(R). Additionally, under the provisions of SFAS 123(R), the Company is required

to include an estimate of the value of the awards that will be forfeited in calculating compensation costs, which is recognized over the requisite service period of the awards on a straight-line basis.

During the year ended December 31, 2007, the Company recorded $1,244,022, or $0.06 per share, of stock-based compensation expense related to all stock options grants, stock awards and employee stock purchases as a result of the adoption of SFAS 123(R). Of this amount, the Company allocated $307,481, $257,218 and $679,323 to research and development, marketing and general and administrative expenses, respectively, based on the department to which the associated employee reported. No related tax benefits of the stock-based compensation expense have been recognized since the inception of the Company.

The Black-Scholes option-pricing model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, the Black-Scholes option-pricing model requires the input of subjective assumptions, including the expected stock price volatility. The following table shows the assumptions used to compute stock-based compensation expense for the stock options granted during the year ended December 31, 2007 using the Black-Scholes option pricing model:

Employee Stock Options	2007	2006	2005
Risk-free interest rate	3.88%-4.80%	4.75%-4.80%	4.00%
Dividend yield	0.00%	0.00%	0.00%
Expected life of options (years)	5.27-6.08	6.08	5.00
Volatility	60.47-65.82%	65.82%	70.00%

The risk-free interest rate assumption was based on the United States Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued. The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. The weighted average expected life of options was calculated using the simplified method as prescribed SAB No. 107, *Share-Based Payment* ("SAB 107"). This decision was based on the lack of relevant historical data due to the Company's limited history. In addition, due to the Company's limited historical data, the estimated volatility also reflects the application of SAB 107, incorporating the historical volatility of comparable companies whose share prices are publicly available.

Based on these assumptions, the weighted average grant-date fair values of stock options granted during the year ended December 31, 2007 was $8.84 per share.

As of December 31, 2007, the total unrecognized compensation expense related to stock options was approximately $7,257,372 and the related weighted-average period over which it is expected to be recognized is approximately 6.83 years.

Prior to January 1, 2006, the Company applied the intrinsic-value-based method of accounting prescribed by APB Opinion 25, and related interpretations including Financial Accounting Standards Board ("FASB") Interpretation No. 44, *Accounting for Certain Transactions involving Stock Compensation — an interpretation of APB Opinion No. 25*, to account for its equity-based awards to employees and directors. Under this method, if the exercise price of the award equaled or exceeded the fair value of the underlying stock on the measurement date, no compensation expense was recognized. The measurement date was the date on which the final number of shares and exercise price were known and was generally the grant date for awards to employees and directors.

Equity instruments issued to non-employees are recorded at their fair value as determined in accordance with SFAS 123(R) and EITF Issue No. 96-18, *Accounting for Equity Instruments That are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods and Services*, ("EITF 96-18") and are periodically revalued as the equity instruments vest and are recognized as expense over the related service period. Through December 31, 2007, the Company issued options in conjunction with various consulting agreements to purchase 290,764 shares of common stock, at exercise prices ranging from $0.22 to $1.08 per share. The options generally vest over a period of up to four years. Expense related to options granted to consultants, as determined under SFAS 123 and EITF 96-18, was $34,720, $176,974 and $43,997, for the years ended December 31, 2007, 2006, and 2005, respectively.

Stock Awards

On September 12, 2007, the Company issued stock awards for 17,500 fully-vested shares of the Company's common stock to its directors under the Company's 2006 Plan. The grant date fair value of the stock awards was $8.47 per share.

Employee Stock Purchase Plan

In connection with the Company's initial public offering in February 2007, it established the employee stock purchase plan. The Company's board of directors adopted the employee stock purchase plan in December 2006, and the stockholders approved the plan in January 2007. A total of 200,000 shares of the Company's common stock were initially made available for sale under the plan. In addition, the employee stock purchase plan provides for annual increases in the number of shares available for issuance under the purchase plan on the first day of each fiscal year, beginning with the Company's 2008 fiscal year, equal to the lesser of (i) 3% of the outstanding shares of the Company's common stock on the last day of the immediately preceding fiscal year; (ii) 300,000 shares; or (iii) such other amount as may be determined by the Company's board of directors.

The initial offering date of the purchase plan was February 15, 2007 and the first purchase occurred on November 15, 2007. As of December 31, 2007, there were 22,683 shares of common stock issued and 177,317 shares remained available for issuance under the purchase plan.

The following table shows the assumptions used to compute stock-based compensation expense for the stock purchased under the purchase plan during the year ended December 31, 2007 using the Black-Scholes option pricing model:

Employee Stock Options	2007
Risk-free interest rate	3.58%-4.64%
Dividend yield	0.00%
Expected life (years)	—
Volatility	45.33-50.66%

As of December 31, 2007, the Company recorded stock-based compensation expense of approximately $63,681 related to the purchase plan.

9. Income Taxes

On July 13, 2006, the FASB issued Financial Interpretation ("FIN") No. 48, Accounting for Uncertainty in Income Taxes — An Interpretation of FASB Statement No. 109. FIN No. 48 clarifies the accounting for uncertainty in income taxes recognized in an entity's financial statements in accordance with SFAS No. 109, Accounting for Income Taxes, and prescribes a recognition threshold and measurement attributes for financial statement disclosure of tax positions taken or expected to be taken on a tax return. Under FIN No. 48, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, FIN No. 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN No. 48 is effective for fiscal years beginning after December 15, 2006.

The Company adopted the provisions of FIN No. 48 on January 1, 2007. There were no unrecognized tax benefits as of the date of adoption and there are no unrecognized tax benefits included in the balance sheet at December 31, 2007 that would, if recognized, affect the effective tax rate.

The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had $0 accrued for interest and penalties on the Company's balance sheets at December 31, 2007 and 2006 and has recognized $0 in interest and/or penalties in the statement of operations for the year ended December 31, 2007.

The Company is subject to taxation in the United States, California and various foreign jurisdictions. The Company's tax years for 1999 and forward are subject to examination by the Federal and California tax authorities due to the carryforward of unutilized net operating losses and research and development credits.

The Company is currently undergoing a Section 382/383 analysis regarding the limitation of net operating loss and research and development credit carryforwards. Until this analysis has been completed the Company has removed the deferred tax assets for net operating losses of $34,796,000 and research and development credits of $2,759,000 generated through 2007 from its deferred tax asset schedule and has recorded a corresponding decrease to its valuation allowance. When this analysis is finalized, the Company plans to update its unrecognized tax benefits under FIN No. 48. The Company expects the Section 382/383 analysis to be completed within the next 12 months. Due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact the Company's effective tax rate.

At December 31, 2007, the Company had Federal, California and foreign income tax net operating loss carryforwards of approximately $87,611,000, 86,350,000 and 1,1976,000, respectively. The Federal and California tax loss carryforwards will begin expiring in 2020 and 2012 resprectively, unless previously utilized. The foreign losses originate from the Compnay's Taiwan subsidiary and expire five years after origination. In addition, the Company has Federal and California research tax credit carryforwards of $1,842,000 and $1,287,000 million, respectively. The Federal research and development credit carryforwards will begin to expire in 2020 unless previously utilized. The California research and development credit carryforwards will carry forward indefinitely until utilized. The Company also has California state manufacturer's investment tax credit carryforwards of $103,000 which will begin to expire in 2011 unless previously utitlized.

Significant components of the Company's deferred tax assets as of December 31, 2007 and 2006 are listed below. A valuation allowance of $680,000 and $19,986,000 at December 31, 2007 and 2006, respectively, has been recognized to offset the net deferred tax assets as realization of such assets is uncertain. Amounts are shown as of December 31, of the respective years:

	2007	2006
Deferred tax assets:		
Net operating loss carryforwards	$ —	$ 17,170,000
Tax credits	—	2,217,000
Other, net	680,000	599,000
Total deferred tax assets	680,000	19,986,000
Valuation allowance for deferred tax assets	(680,000)	(19,986,000)
	$ —	$ —

As of December 31, 2007, the Company had federal, state and foreign net operating loss carryforwards of approximately $87,611,000, $86,350,000 and $1,976,000, respectively. The federal and state tax loss carryforwards will begin expiring in 2020 and 2012, respectively, unless previously utilized. The foreign losses originate from the Company's subsidiary in Taiwan. The losses from the Company's subsidiary in Taiwan expire five years after origination. The Company also had federal research tax credit carryforwards of approximately $1,842,000, which will begin to expire in 2020, unless previously utilized. As of December 31, 2007, the Company had California state research tax credit carryforwards of approximately $1,287,000, which do not expire and California state manufacturer's investment tax credit carryforwards of approximately $103,000, which will begin to expire in 2011, unless previously utilized.

Pursuant to Sections 382 and 383 of the Internal Revenue Code, annual use of the Company's net operating loss and credit carryforwards may be limited in the event of a cumulative change in ownership of more than 50% within a three-year period.

10. Employee Benefit Plan

Effective January 1, 2000, the Company established a 401(k) plan covering substantially all employees. Employees may contribute up to 100% of their compensation per year (subject to a maximum limit prescribed by federal tax law). The Company may elect to make a discretionary contribution or match a discretionary percentage

of employee contributions. As of December 31, 2007 and 2006, the Company had not elected to make any contributions to the 401(k) plan.

11. Subsequent Event

As of December 31, 2007, the Company held $14.2 million of ARS with stated maturity dates ranging from 2022 to 2037 and reset dates primarily less than 30 days. The recent negative conditions in the global credit markets have prevented some investors from liquidating their holdings, including their holdings of ARS. As of March 21, 2008, the Company held two ARS, representing approximately $1.5 million. There was insufficient demand at auction for these two ARS. As a result, these affected securities are currently not liquid, and the Company could be required to hold them until they are redeemed by the issuer or to maturity. In the event the Company needs to access the funds that are in an illiquid state, it will not be able to do so without a loss of principal, until a future auction on these investments is successful, the securities are redeemed by the issuer or they mature. At this time, management has not obtained sufficient evidence to conclude that these investments are impaired or that they will not be settled in the short term, although the market for these investments is presently uncertain. If the credit ratings of the security issuers deteriorate and any decline in market value is determined to be other-than-temporary, the Company would be required to adjust the carrying value of the investment through an impairment charge.

Exhibit 31.1

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

I, Michael N. Chang, certify that:

1. I have reviewed this annual report on Form 10-K of Optimer Pharmaceuticals, Inc.;

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

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

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

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including any consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 26, 2008

/s/ Michael N. Chang
Michael N. Chang
President and Chief Executive Officer

Exhibit 31.1

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

I, Michael N. Chang, certify that:

1. I have reviewed this annual report on Form 10-K of Optimer Pharmaceuticals, Inc.;

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

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

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

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including any consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 26, 2008

/s/ Michael N. Chang
Michael N. Chang
President and Chief Executive Officer

Exhibit 31.2

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

I, John D. Prunty, certify that:

1. I have reviewed this annual report on Form 10-K of Optimer Pharmaceuticals, Inc.;

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

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

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

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including any consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 26, 2008

/s/ John D. Prunty
John D. Prunty
Vice-President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32

CERTIFICATION

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. § 1350, as adopted), Michael N. Chang, the Chief Executive Officer of Optimer Pharmaceuticals, Inc. (the "Company"), and John D. Prunty, the Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the year ended December 31, 2007, to which this Certification is attached as Exhibit 32 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Annual Report and results of operations of the Company for the period covered by the Annual Report.

Dated: March 26, 2008

/s/ Michael N. Chang	/s/ John D. Prunty
Michael N. Chang	John D. Prunty
Chief Executive Officer	Chief Financial Officer
(Principal Executive Officer)	(Principal Financial and Accounting Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filling of the Company under the Securities Act of 1933, as amended, or Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

END