

## OPTIMER PHARMACEUTICALS, INC.

2012 Stockholder Letter



Hank McKinnell, Ph.D.
Chairman of the Board and
Chief Executive Officer

## Dear Stockholders,

In 2012, we continued advancing our vision for DIFICID\* (fidaxomicin) tablets for patients with Clostridium difficile-associated diarrhea (CDAD). DIFICID is distinguished as the first drug approved by the FDA to treat CDAD in more than 25 years and the only FDA-approved antibacterial drug for CDAD proven to be superior to vancomycin in sustained clinical response at 25 days beyond the end of treatment.

2012 was our first full year of DIFICID sales in the United States, and it marked the transition from launching a new product to implementing new strategies to optimize the DIFICID market opportunity. In 2012, we recognized \$62.4 million in net product sales in the United States and Canada, and we have recorded \$83.9 million in cumulative net product sales since launch through the end of 2012.

Despite our successful launch in 2011 and into early 2012. we experienced a slowdown in growth, primarily as a result of sensitivity to the DIFICID acquisition cost both in hospitals and for patients in the retail pharmacy setting. In response to the cost pressures increasingly placed on health care providers in the hospital setting and the resulting challenges for a new product like DIFICID, we implemented several initiatives to help overcome the key barriers to DIFICID adoption and patient access. Our strategy to meet this challenge is comprised of a few important components:

• We applied for, and, in August 2012, DIFICID became the first oral medication to be awarded a New Technology Add-on Payment (NTAP) by the Centers for Medicare & Medicaid Services (CMS). CMS introduced the NTAP program in 2001 to support timely access to innovative therapies used to treat Medicare beneficiaries in the inpatient setting that provide a substantial clinical improvement over existing therapies. The add-on payment facilitates Medicare beneficiaries' access to new, clinically superior technologies while the reimbursement rates under the inpatient prospective payment system are updated. Hospitals may receive a maximum add-on payment of \$868 in fiscal year 2013 for qualifying Medicare inpatient CDAD cases treated with DIFICID and exceeding the Medicare Severity Diagnosis Related Group reimbursement. The \$868 maximum payment may not apply to every case involving DIFICID. The maximum amount available for fiscal year 2014 has not yet been determined.

- On October 1, 2012, we launched a hospital contracting program designed to address price as a barrier to prescribing DIFICID for hospital inpatients. This program reduced the acquisition cost of DIFICID by 25% in acute care hospitals for all inpatients. The discount is intended to expand the use of DIFICID in acute-care hospitals.
- In August 2012, we initiated the DIFICID Rx Assist™ program, designed to support patient access by addressing prescription abandonment of DIFICID in the retail segment. This program facilitates continuity of care by providing patients with a variety of information to support patient access to DIFICID, including benefits investigations, prior authorizations and the claims appeals processes. Early in 2013, we launched the DIFICID® Co-Pay Assistance Program as part of DIFICID Rx Assist to help eligible commercially-insured patients who have difficulty affording their co-pay for DIFICID. We have seen a positive impact on prescription abandonment rates at the retail level with the DIFICID Rx Assist program, and the focus in 2013 is to enroll more patients into the program.

Separate from our product-specific efforts, we have also embarked on educational initiatives both on a national and hospital-specific level to help institutions better understand the impacts of disease burden. We commissioned a research analysis of Medicare data detailing the incidence of readmission for Medicare inpatients treated for *Clostridium difficile* infection (CDI). The data suggest a link between CDI recurrence, patient readmission and burden of CDI treatment cost in hospitals. We introduced this national and hospital-by-hospital data analysis in late 2012 and have, to date, presented the findings to hundreds of hospital physicians and administrators to help them better understand the burden of CDI.

# 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

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

For the fiscal year ended December 31, 2012

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

For the transition period from

te

Commission file number: 001-33291

## Optimer Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or Other Jurisdiction of Incorporation or Organization)

33-0830300

(I.R.S. Employer Identification No.)

101 Hudson Street, Suite 3501, Jersey City, NJ 07302

(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: (201) 333-8819

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 Select 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 whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files): Yes  $\boxtimes$  No  $\square$ 

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

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, 2012 (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 Select Market, was \$724.313.291.

The number of outstanding shares of the registrant's common stock, par value \$0.001 per share, as of March 11, 2013 was 47,900,542.

#### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Definitive Proxy Statement for our 2013 Annual Meeting of Stockholders are incorporated by reference in Part III of this report.

### **OPTIMER PHARMACEUTICALS**

## FORM 10-K—ANNUAL REPORT For the Fiscal Year Ended December 31, 2012

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#### PART I

### **Cautionary Note Regarding Forward-Looking Statements**

This report and other documents we file with the U.S. Securities and Exchange Commission, or SEC, contain forward-looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business, 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 filing of this report, whether as a result of new information, future events, changes in assumptions or otherwise.

#### Item 1. Business

#### Overview

We are a global biopharmaceutical company currently focused on commercializing our antibiotic product DIFICID® (fidaxomicin) tablets in the United States and Canada, and developing other fidaxomicin products in the United States and worldwide, both by ourselves and with our partners and licensees. DIFICID, a macrolide antibacterial drug, was approved by the U.S. Food and Drug Administration, or FDA, on May 27, 2011, for the treatment of Clostridium difficile-associated diarrhea, or CDAD, in adults 18 years of age and older. CDAD is the most common symptom of Clostridium difficile infection, or CDI. We market DIFICID in the United States through our own sales force and through our co-promotion agreement with Cubist Pharmaceuticals, Inc., or Cubist.

We continue to pursue regulatory approval for, and commercialization of, fidaxomicin in other geographies outside the United States and Canada through various collaboration partners. DIFICLIR<sup>TM</sup> (fidaxomicin) is approved in Europe for the treatment of adults suffering from CDI. In June 2012, our collaboration partner, Astellas Pharma Europe Ltd., or APEL, achieved the first sales of DIFICLIR in certain of its European territories. In June 2012, our subsidiary, Optimer Pharmaceuticals Canada, Inc., or Optimer Canada, began marketing DIFICID in Canada. We have entered into agreements with Astellas Pharma Inc., or Astellas Japan, and with Specialised Therapeutics Australia Pty. Ltd, or STA, for the development and commercialization of fidaxomicin in Japan and in Australia and New Zealand, respectively. In November 2012, we entered an exclusive agreement with AstraZeneca UK Limited, or AstraZeneca, to commercialize fidaxomicin for the treatment of CDI in Latin America, including Brazil, Central America, Mexico and the Caribbean.

CDAD is the most common nosocomial, or hospital acquired, diarrhea and is a significant medical problem in hospitals and long-term care facilities. In addition, CDAD is beginning to emerge in the community among people previously at low risk for the disease. CDAD is a serious illness resulting from infection of the inner lining of the colon by *C. difficile* bacteria, which produce toxins that cause inflammation of the colon, severe diarrhea and, in the most serious cases, death. Certain subpopulations, such as older patients, transplant patients, patients taking concomitant antibiotics and cancer patients, are at a higher risk of contracting CDAD.

DIFICID is the first drug approved by the FDA for the treatment of CDAD in more than 25 years. In two large Phase 3 clinical trials, DIFICID reached its primary endpoint, with non-inferiority in clinical response rates at the end of treatment compared to oral vancomycin (88% vs. 86% and 88% vs. 87%, p=NS, for DIFICID and vancomycin, respectively). In addition, DIFICID was designated by the FDA as superior to vancomycin, the only other agent with an indication for the treatment of CDAD, in sustaining clinical response through 25 days beyond the end of treatment (70% vs. 57%, p=0.0011; 72% vs. 57%, p=0.0004, for DIFICID and vancomycin, respectively). Sustained clinical response was defined as clinical response at the end of treatment and survival without proven or suspected CDAD recurrence through the 25-day follow-up period. DIFICID is the only FDA-approved antibacterial drug proven to be superior to vancomycin in sustained clinical response for CDAD.

Recurrence rates in the Phase 3 clinical trials among patients who had initial clinical response were statistically significantly lower in those treated with DIFICID. In the modified intention-to-treat, or mITT, population, recurrence rates were 15.4% for

DIFICID versus 25.3% for vancomycin (p=0.005) in one trial and 12.7% for DIFICID versus 26.9% for vancomycin (p=0.0002) in the other trial.

In August 2012, the Centers for Medicare & Medicaid Services, or CMS, granted a new technology add-on payment, or NTAP, for DIFICID administered in the inpatient hospital setting to treat qualifying Medicare Part A patient cases with CDAD. Introduced in 2001, the add-on payment is designed to support timely access to innovative therapies used to treat Medicare beneficiaries in the inpatient setting that provide a substantial clinical improvement over existing therapies. Acute care hospitals participating in the inpatient prospective payment system are eligible for an additional reimbursement of up to \$868 per case in fiscal year 2013 where cost of the entire case exceeds the Medicare Severity Diagnosis Related Group payment amount. The DIFICID add-on payment granted by CMS represents a policy change, as DIFICID is the first, and only, oral medication not associated with a procedure code ever approved for an NTAP. The add-on payment is a special additional payment for qualifying Medicare cases and is intended to assist in addressing cost as a barrier to appropriate use. The policy is effective for hospital discharges occurring on or after October 1, 2012 and will continue for two to three years.

Subject to FDA discussion and review, we intend to pursue new areas where we perceive opportunities exist to expand the DIFICID label to include new indications. We believe prophylactic use of DIFICID represents a potential opportunity for significant incremental market expansion. For example, in October 2012, we initiated a Phase 3 clinical trial for the prevention of CDAD in patients undergoing hematopoietic stem cell transplantation, or HSCT, which is often referred to as bone marrow transplantation. CDAD can be a serious complication of HCST, leading to longer hospital stays and increased cost of care.

We were incorporated in November 1998. In addition to Optimer Canada, we established subsidiaries in Bermuda and Europe in 2012 to facilitate our international expansion. We sold our remaining interest in OBI Pharma, Inc., formerly known as Optimer Biotechnology, Inc, or OBI, in 2012 for \$60.0 million in gross proceeds. In this report, "Optimer Pharmaceuticals," "Optimer," "we," "us" and "our" refer to Optimer Pharmaceuticals, Inc., Optimer Canada and our other international subsidiaries on a consolidated basis, unless the context otherwise requires. Our principal executive offices are in Jersey City, New Jersey, and we operate a facility in San Diego, California. We maintain an internet website at <a href="https://www.optimerpharma.com">www.optimerpharma.com</a>, which includes links to reports we have filed with the SEC. Any information that is included on, or linked to, our internet site is not a part of this report or any registration statement that incorporates this report by reference. Our filings may be read and copied at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-732-0330. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that website is <a href="https://www.sec.gov">www.sec.gov</a>.

### **Our Business Strategy**

Our goal is to establish ourselves as a leading hospital specialty products-based biopharmaceutical company focused on the global commercialization of fidaxomicin. To achieve this objective, our strategy includes the following key elements:

- Build a branded anti-infective franchise for DIFICID in the United States and Canada. We intend to continue the
  successful commercialization of DIFICID by supporting increased patient access, continuity of care, formulary access
  across payors, hospitals and long-term care facilities and the adoption of first-line DIFICID use in appropriate patients.
- Establish collaborations and distribution arrangements in international markets. We intend to continue to secure fidaxomicin marketing authorization in markets outside the United States where C. difficile has emerged as a serious health problem and pursue commercialization in these markets by evaluating partnering alternatives to market our products as appropriate. To date, we have entered into collaborations with: APEL for Europe; Astellas Japan for Japan; STA for Australia and New Zealand; and AstraZeneca for Latin America.
- Develop DIFICID for additional indications. We believe there are opportunities to expand DIFICID's label to address unmet medical needs related to CDI that can provide clinical benefit to patients. We plan to pursue, subject to FDA discussion and review, such opportunities which we believe have significant market expansion potential. We currently are evaluating prophylactic use of DIFICID in patients undergoing bone marrow transplantation, who are at risk for CDAD and where CDAD has a significant impact on the patient and the disease-associated burden. Other opportunities exist in oncology patients, patients with multiple recurrences of CDAD and pediatric patients.
- Selectively acquire or in-license additional hospital specialty products for development and/or commercialization. In order to maximize the value of our hospital franchise and the investment in our commercial infrastructure, we intend to opportunistically consider the expansion of our product portfolio by selectively acquiring or in-licensing additional hospital products or product candidates. We believe the U.S. hospital market provides an opportunity for a biopharmaceutical company with a modestly sized sales infrastructure to successfully market innovative medicines.

#### **Commercialization Efforts**

We market DIFICID in the United States through our own sales force and through our co-promotion agreement with Cubist. In 2011, we completed the establishment of our commercial infrastructure, including key additions to our senior management team, to commercialize DIFICID in the United States. Our infrastructure includes a sales force of approximately 116 hospital sales specialists, in addition to experienced commercial and marketing management. Our commercialization functions include institutional formulary adoption, payor access/coverage, sales and promotion.

Our commercialization efforts are directed at physicians, pharmacists, administrators and others throughout the hospital and long-term care settings. Our primary commercial efforts are focused on the hospital, where the majority of initial prescribing decisions for DIFICID are made, as a means of driving broader use of DIFICID in other segments such as long-term care and retail. Our sales representatives primarily target approximately 1,200 hospitals, although approximately 2,750 hospitals have ordered DIFICID. In October 2012, we instituted a hospital contracting strategy that provides a discount to hospitals for DIFICID use in the acute care inpatient setting.

On April 5, 2011, we entered into a co-promotion agreement with Cubist, pursuant to which we engaged Cubist as our exclusive partner for the promotion of DIFICID in the United States. Under the terms of the agreement, Cubist and we have agreed to co-promote DIFICID to physicians, hospitals, long-term care facilities and other healthcare institutions, as well as jointly to provide medical affairs support for DIFICID. In addition to DIFICID, Cubist markets CUBICIN® and ENTEREG®. With the establishment of our own field force, we estimate that the vast majority of our approximately 1,200 target hospitals are covered by both a Cubist representative and an Optimer representative. As such, we currently do not anticipate renewing the co-promotion agreement when it expires on July 31, 2013, and will evaluate expanding our field force to detail the hospitals currently covered only by a Cubist representative.

We are pursuing regulatory approval and commercialization of fidaxomicin in other geographies outside the United States and Canada through various collaboration partners.

#### Distribution

We sell DIFICID through wholesalers that have agreed to be authorized distributors of record of DIFICID in the United States. These wholesalers sell DIFICID to hospitals and long-term care facilities, in addition to retail and specialty pharmacies in the United States. We outsource a number of our product supply chain services to third-party vendors, including services related to warehousing and inventory management, distribution, chargeback processing and accounts receivable management.

We introduced DIFICID Rx Assist<sup>TM</sup> in the third quarter of 2012 to help facilitate the process of filling patients' prescriptions in the retail setting. We sell product directly to Advanced Care Scripts, or ACS, a part of Omnicare Specialty Care Group, which manages the DIFICID Rx Assist program on our behalf. By selling product directly to ACS, we can ensure that the DIFICID Rx Assist program has an appropriate level of inventory available to ship to patients at all times.

The following table details the percentage of our gross product sales to distribution customers who represented 10% or more of our gross product sales in 2012 and 2011 and the percentage of our accounts receivable related to such customers as of December 31, 2012 and 2011:

	Gross Produc	t Sales	Accounts Receivable		
	2012	2011	2012	2011	
AmerisourceBergen Corporation	22%	23%	17%	21%	
Cardinal Health, Inc	36%	43%	39%	30%	
McKesson Corporation	35%	30%	37%	46%	
	93%	96%	93%	97%	

These three customers represented substantially all of our gross product sales in the United States. We do not believe that the loss of any one of these customers would have a material adverse effect on product sales because we expect that product sales would shift to other customers. However, the loss of one of these three customers could increase our dependence on the remaining two primary customers.

#### **Our Market Opportunity**

Our primary market is the U.S. hospital market, which consists of approximately 7,000 acute care hospitals. U.S. hospitals purchased over \$10 billion of antibiotics in 2009. Many antibiotics used to treat infections have well-documented shortcomings. For example, certain antibiotics often fail to reach sufficient concentrations at the site of infection to adequately eliminate harmful bacteria. Certain of these antibiotics also have 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 lead to death. Patients also often fail to comply with antibiotic 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 and Product Candidates**

We believe that fidaxomicin offers, or may offer, advantages over existing antibiotics. We also believe that the markets for fidaxomicin present us with significant commercial opportunities.

Our ability, or our licensees' abilities, to obtain additional regulatory approvals for fidaxomicin may require us or our licensees to successfully complete additional clinical development and demonstrate, through data submissions, the safety and efficacy of the product candidate to the satisfaction of foreign regulatory authorities. 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 or product candidate portfolio consists of the following:

roduct or Product 'andidate Geography				Commercial Rights
DIFICID (fidaxomicin) tablets	United States	CDAD Commercial		Optimer
DIFICID	Canada	CDI	Commercial	Optimer Canada
DIFICLIR (fidaxomicin)	Austria, the Czech Republic, Denmark, Finland, France, Germany, Hungary, Iceland, the Netherlands, Norway, Portugal, Slovenia, Spain, Sweden and the United Kingdom	Republic, Denmark, land, France, Germany, Hungary, Iceland, the Netherlands, Norway, rtugal, Slovenia, Spain, weden and the United		APEL
DIFICLIR	Other European Markets (EMA Markets)	CDI	EMA Approved. Pricing and Reimbursement Negotiations	APEL
DIFICLIR	Other APEL Territories	CDI	Registration	APEL
Fidaxomicin	Australia/New Zealand	CDI	Registration	STA
Fidaxomicin	Latin America/Caribbean	CDI	Registration	AstraZeneca
Fidaxomicin	Japan	CDI	Phase 1	Astellas Japan

#### Life-cycle Management

	DIFICID	United States	CDAD Prophylaxis in HSCT Patients	Phase 3b(1)	Optimer
4 (19) 13 (19)	DIFICID	United States and Europe	CDAD in Pediatric Patients	PK Trial Initiated/Phase 3 Trial Planned(1) (2)	Optimer/APEL
erika Periodok Periodok	DIFICID	United States	CDAD Multiple Recurrence	Phase 3 Trial Planned(1) (2)	Optimer

<sup>(1)</sup> We intend that data from these Phase 3 trials, if successful, will be presented to the FDA as part of an sNDA in order to expand the DIFICID label.

#### Fidaxomicin

Overview. We developed fidaxomicin for the treatment of infection caused by C. difficile bacteria. C. difficile is the most common cause of infectious diarrhea in healthcare settings. Fidaxomicin is a differentiated antibacterial drug for the treatment of CDAD in adults 18 years of age or older. CDAD is the most common symptom of C. difficile infection. Fidaxomicin has potent activity against C. difficile and moderate activity against certain other gram-positive organisms, such as Enterococcus and Staphylococcus, but it is virtually inactive against Gram-negative organisms and yeast. Fidaxomicin is bactericidal in vitro and has a unique mechanism of action, exerting its activity by inhibiting RNA polymerase, a bacterial enzyme.

Clostridium difficile Infection. CDI has become a significant medical problem in hospitals, in long-term care facilities and in the community and is estimated to afflict more than 700,000 people each year in the United States. C. difficile has surpassed methicillin-resistant Staphylococcus aureus, or MRSA, as the leading cause of healthcare-acquired infections in community hospitals. CDI is a serious illness resulting from infection of the inner lining of the colon by C. difficile bacteria that produce toxins causing inflammation of the colon, severe diarrhea and, in the most serious cases, death. Patients typically develop CDI from the use of broad-spectrum antibiotics that disrupt normal gastrointestinal (gut) flora, thus allowing C. difficile bacteria to flourish and produce toxins. C. difficile is a spore forming bacterium, creating spores excreted in the environment of the patients that can survive for months on dry surfaces in hospital rooms such as beds and doors, and can contaminate other patients by fecal-oral transmission through the hands of healthcare workers.

In addition to fidaxomicin, therapeutic options for CDAD include the use of metronidazole off-label and oral vancomycin, the latter being the only other agent that is FDA-approved for the treatment for CDAD. However, approximately 20% to 30% of CDAD patients who initially respond to these older treatment options experience a clinical recurrence following cessation of treatment.

Primary risk factors for CDI include broad-spectrum antibiotic use (such as cephalosporins and fluoroquinolones), age (over 65), immune compromised status (such as oncology patients), presence of multiple comorbidities and prolonged stay in a healthcare facility. Incidence and severity of CDI cases are increasing with growing rates of recurrence, septic shock, toxic megacolon and intestinal perforation. *C. difficile*-associated mortality rates increased 400% between 2000 and 2007 in the United States. The elderly are particularly vulnerable, as over two-thirds of CDI patients are 65 years and older. Rates of morbidity and mortality increase with patient age, with a mortality rate as high as 14% in elderly patients. The increasing incidence and mortality of CDI, along with high rates of both treatment failures and recurrences with earlier therapies, has resulted in greater awareness and concern about CDI among medical professionals and public health officials.

We believe that the incidence of CDI may be higher than what is reported because many hospitals are not required to and do not report incidence of CDI. According to the Centers for Disease Control and Prevention, CDI rates increased 200% for hospitalized patients aged over 65 years from 1996 to 2009. Data published in 2012 by the Agency for Healthcare Research and Quality Healthcare Cost and Utilization Project (HCUP) showed that in 2009, there were 336,600 hospitalizations that involved CDI, which is nearly 1% of all hospital stays.

Reports indicate that the incidence of community-acquired CDI cases also may be increasing and CDI has been observed in populations previously considered to be at low risk. In one population-based U.S. study, community-acquired CDI accounted for 41% of all definite CDI cases. The same study showed that the incidence of both community-acquired and hospital-acquired CDI increased significantly over the study period. Compared to those with hospital-acquired CDI, patients with community-acquired infection were younger, more likely to be female, had lower comorbidity scores and were less likely to have severe infection or to have been exposed

<sup>(2)</sup> FDA requirement or commitment.

to antibiotics. The study demonstrated that CDI affects populations previously thought to be at low risk, including young adults and children, and those who lack the traditional risk factors of recent hospitalization or exposure to antibiotics.

Generally, CDI results in longer hospital stays and increases average patient cost which often is not fully reimbursed to the hospital. Compared to the average inpatient, CDI patients are considerably sicker and their cases more complex. Patients with CDI hospital stays are more severely ill than the general hospital population, with longer lengths-of-stay and higher death rates.

In more complicated cases of CDI, hospitalization may be prolonged by up to two weeks. One analysis showed that the adjusted mean cost for CDI cases was \$15,400 higher than for cases without CDI, and the adjusted mean length of hospital stay was over eight days longer. In certain populations, such as surgical patients, the costs can be even higher and lengths of stay up to 16 days longer. The overall costs attributable to CDI cases in the U.S. healthcare system are estimated at \$8.2 billion per year.

We believe that DIFICID addresses an unmet medical need for patients with CDAD and provides economic value to the healthcare system:

- DIFICID is the first drug approved by the FDA to treat CDAD in more than 25 years and has demonstrated comparable initial efficacy and a superior sustained clinical response through 25 days after the end of treatment for CDAD versus vancomycin, the only other drug FDA approved drug for the treatment of CDAD.
- DIFICID is the first, and only, oral medication to qualify for a new technology add-on payment from CMS. The NTAP program is only available to new technologies demonstrating a substantial clinical improvement and meeting specific cost thresholds.

We believe DIFICID's profile provides an opportunity to develop significant market penetration for first-line use in CDAD patients. Additionally, we believe there are opportunities to expand DIFICID's label to address unmet medical needs related to CDAD and provide value to patients and the healthcare system.

Alternative Treatments and Limitations. Metronidazole generally is used for patients in the United States and Europe experiencing their first mild-to-moderate episode or first recurrent episode of CDAD. Metronidazole is a generic drug that is used offlabel to treat CDAD due to its low cost and historical efficacy. The guideline-recommended treatment regimen for metronidazole is 500 mg three times per day, for 10 to 14 days.

Vancomycin is used in the United States and also in Europe and Japan for the treatment of CDAD. As a result of its broad antibacterial activity, intravenously administered vancomycin frequently is used for certain other life-threatening infections caused by multi-drug resistant bacteria such as MRSA. 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 CDAD except for patients who are not responding to metronidazole, for patients with severe symptoms or for patients with risk factors that are predictive of negative treatment outcomes.

Both metronidazole and vancomycin have shortcomings as treatments for CDAD including:

- Limited Efficacy. A controlled study conducted in North America and reported in 2007 showed that approximately 19% of CDAD patients treated with oral vancomycin and 28% of CDAD patients treated with metronidazole do not respond to therapy, and these patients are at risk of developing more severe CDAD.
- High Recurrence Rate. Approximately 25% of CDAD patients who initially respond to oral vancomycin and approximately 27% of CDAD 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 CDAD in some hospitals due to concerns over the development of cross-resistant bacteria, including vancomycin-resistant *enterococcus*, or VRE, and vancomycin-resistant *Staphylococcus*, which can cause other serious nosocomial infections.
- Adverse Side Effects. Metronidazole, which is systemically absorbed, may result in adverse side effects and complications, including seizures, toxic reactions to alcohol, leukopenia, neuropathy, unpleasant taste and dry mouth.
- Inducement of CDI. Oral vancomycin and metronidazole are both broad-spectrum antibacterials that disrupt the normal gut *flora*, which help suppress the growth of *C. difficile*.

Less Convenient Dosing and Compliance. The current treatment regimen for oral vancomycin and metronidazole is less
convenient, as both must be administered three or four times per day for a minimum of 10 days, which may result in
lower levels of patient compliance.

Fidaxomicin Differentiating Characteristics. Fidaxomicin is a unique antibacterial drug consisting of an 18-member macrocyclic ester ring structure. After receiving expedited priority review, fidaxomicin was approved by the FDA in May 2011 for the treatment of CDAD in adults 18 years of age or older.

Fidaxomicin has significant differentiating features, including:

- an initial response rate comparable to vancomycin and a designation by the FDA as superior in sustained clinical response (enduring response) through 25 days after the end of treatment;
- a targeted antimicrobial spectrum primarily limited to species of clostridia, including C. difficile;
- bactericidal activity against C. difficile in vitro;
- limited disruption of normal gut *flora* both *in vitro* and in fecal profiling clinical studies, which may contribute to the lower likelihood of CDAD recurrence;
- lower risk of colonization by VRE with fidaxomic (7%) than vancomycin (31%);
- minimal systemic absorption, acting locally in the gastrointestinal tract;
- post-antibiotic effect of 6 to 10 hours;
- twice daily dosing regimen;
- no in vitro cross-resistance with other classes of antibacterial drugs; and
- no significant drug interactions, no contra-indications and no dose adjustment necessary in patients over 65 years old or in patients with renal or hepatic impairment.

#### Clinical Development

Phase 3 Pivotal Trials.

DIFICID is the first drug approved by the FDA for the treatment of CDAD in more than 25 years. In two large Phase 3 clinical trials, DIFICID reached its primary endpoint successfully, with non-inferiority in clinical response rates at the end of treatment compared to oral vancomycin (88% vs. 86% and 88% vs. 87%, p=NS, for DIFICID and vancomycin respectively). In addition, DIFICID was designated by the FDA as superior to vancomycin, the only other agent with an indication for the treatment of CDAD, in sustaining clinical response through 25 days beyond the end of treatment (70% vs. 57%, p=0.0011; 72% vs. 57%, p=0.0004, for DIFICID and vancomycin respectively). Sustained clinical response was defined as clinical response at the end of treatment and survival without proven or suspected CDAD recurrence through the 25-day follow-up period. DIFICID is the only FDA-approved antibacterial drug proven to be superior to vancomycin in sustained clinical response for CDAD.

Recurrence rates in the Phase 3 clinical trials among patients who had initial clinical response were statistically significantly lower in those treated with DIFICID. In the modified intention-to-treat population, recurrence rates were 15% for DIFICID versus 25% for vancomycin (p=0.0005) in one trial and 13% for DIFICID versus 27% for vancomycin (p=0.0002) in the other trial.

Results from the Phase 3 trials are summarized below:

		Trial 1 -	Study 101.1.C.003	3		Trial 2 - St	tudy 101.1.C.004	
	Analysis	DIFICID (%)	Vancomycin (%)	Difference (95% CI)	Analysis	DIFICID (%)	Vancomycin (%)	Difference (95% CI)
Clinical Response	mITT	88%	86%	2.6	mITT	88%	87%	1.0
at End of				(-2.9 to 8.0)				(-4.8 to 6.8)
Treatment				p=NS				p=NS
Sustained	mITT	70%	57%	12.7	mITT	72%	57%	14.6
Response at				(4.4 to 20.9)				(5.8  to  23.3)
Follow-up				p=0.0011				p=0.0004
Recurrence	mITT	15%	25%	<b>-</b> 9.9	mITT	13%	27%	-14.2
				(-16.6 to -2.9)				(-21.4 to -6.8)
				p=0.005				p=0.0002

Further analysis of the results from the Phase 3 trials and several recent publications demonstrated other potential advantages of fidaxomicin:

- in patients with more pronounced diarrhea (diarrhea that did not resolve in the first 24 hours of therapy), fidaxomicin was associated with a faster time to resolution than vancomycin (79 hours vs. 105 hours, p=0.056);
- in patients who did not receive either vancomycin or metronidazole in the 24-hour pre-trial enrollment period, the difference in recurrence rate between fidaxomicin and vancomycin was more pronounced than in the overall patient population at 10.9% vs. 24.3%, respectively;
- CDI recurrence occurred significantly later in patients treated with fidaxomic with only 3% and 9% recurrence rates versus 14% and 20% recurrence rates for vancomycin, at 10 and 20 days post-treatment, respectively;
- fidaxomicin was less likely than vancomycin to promote VRE colonization in patients treated for CDI, which we believe may be due to inhibitory activity of fidaxomicin against many VRE strains and fidaxomicin's relative sparing of the intestinal *flora* including *Bacteroides* bacteria. The analysis showed that only 7% of patients treated with fidaxomicin acquired VRE versus 31% of vancomycin-treated patients (p<0.001);
- fidaxomicin was significantly more effective than vancomycin in achieving clinical cure in the presence of concomitant antibiotics, or CA, therapy and in preventing recurrence regardless of CA use;
- a meta-analysis of the two pivotal trials showed that in the full analysis set (ITT population), fidaxomicin reduced persistent diarrhea, recurrence or death by 40% (95% confidence interval [CI], 26%—51%; p < .0001) compared with vancomycin through day 40. Through day 12, fidaxomicin reduced persistent diarrhea or death by 37%; and
- fidaxomicin is able to inhibit *C. difficile's* production of spores, the most readily transmissible form of *C. difficile*, in vitro and that fidaxomicin inhibits toxin production by *C. difficile in vitro*.

We expect to continue to support peer reviewed publication of additional data and analyses related to fidaxomicin, as well as presentation of such data and analyses at a variety of medical and scientific meetings and conferences.

#### Clinical Studies/Label Expansion

In 2012, we initiated two new clinical studies of DIFICID. The first is a Phase 2a open-label, uncontrolled, safety, tolerability and pharmacokinetic study in pediatric subjects with CDI (NCT01591863). This study is intended to recruit 32 subjects ranging in age from six months to 18 years.

We believe there are opportunities to expand DIFICID's label to address unmet medical needs related to CDI that can provide economic value to the healthcare system. We plan to pursue, subject to FDA discussion and review, such opportunities where we view significant potential for market expansion.

One area that we believe presents an important label expansion opportunity is the prophylactic use of DIFICID in certain patient populations. We believe DIFICID may be effective not only for treating CDAD, but also in preventing CDAD in patients at high risk of developing CDAD. There currently is no therapeutic drug approved for the prevention of CDAD. We believe

fidaxomicin may provide safe, potent and narrow-spectrum bactericidal activity against *C. difficile*, thereby protecting high-risk patients while limiting disruption to normal, beneficial gut *flora*.

The second study initiated in 2012 is a Phase 3b, multicenter, randomized, double-blind, controlled clinical trial comparing fidaxomicin to placebo in the prophylaxis of CDI in subjects undergoing HSCT and receiving fluoroquinolone prophylaxis (NCT01691248). Subjects undergoing HSCT will be treated once-daily with fidaxomicin 200 mg for up to 40 days (through seven days post-engraftment or past the end of fluoroquinolone prophylaxis, whichever is later). The primary endpoint is occurrence of CDI through 30 days post-treatment. The secondary endpoint is occurrence of CDI through 60 days post-treatment. This study is expected to enroll approximately 340 patients but may be readjusted for size in a blinded interim analysis at 50% enrollment. HSCT patients generally are at risk for CDAD, and CDAD has a significant impact on the patient and the disease-associated cost burden. This study was initiated in October 2012.

License from Par Pharmaceuticals, Inc.

In February 2007, we repurchased the rights to develop and commercialize fidaxomicin in North America and Israel from Par under a prospective buy-back agreement. We paid Par a \$5.0 million milestone payment in June 2010 for the successful completion of our second pivotal Phase 3 trial for fidaxomicin. We are obligated to pay Par a 5% royalty on any net sales by us, our affiliates or our licensees of fidaxomicin in North America and Israel, including Cubist, and a 1.5% royalty on any net sales by us or our affiliates of fidaxomicin in the rest of the world. In addition, we are required to pay Par a 6.25% royalty on net revenues we receive related to fidaxomicin in connection with the licensing of our right to market fidaxomicin in the rest of the world, such as the licenses we have granted to our partners in territories outside the United States and Canada. 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.

#### **Other Product Candidates**

We have out-licensed rights to two development programs.

Solithromycin (CEM-101): Macrolide and Ketolide Antibiotics

Macrolide antibiotics are marketed for the treatment of upper and lower respiratory tract infections, or RTIs. 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 is now resistant to currently available macrolides and ketolides. The leading product candidate developed by us, solithromycin, was effective against these resistant bacterial strains according to a preclinical study conducted by the Institute for Medical Microbiology. Cempra Pharmaceuticals, Inc., or Cempra, has licensed from us a library of approximately 500 macrolides related to this product candidate.

CEM-101 has been shown to possess potent activity against multi-drug resistant Streptococcus pneumoniae and Streptococcus pyogenes, common RTI pathogens. A preclinical study showed that solithromycin was orally active with potent efficacy in animal models after once-a-day administration. Cempra recently initiated a global Phase 3 clinical trial of orally-administered solithromycin in patients with community-acquired bacterial pneumonia. In Phase 2 trials, solithromycin showed a favorable safety profile in over 400 patients. We may receive milestone payments as product candidates are developed and/or codeveloped 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.

OPT-822/821: Cancer Immunotherapy for Breast Cancer

In 2009, under an intellectual property assignment and license agreement, we assigned to OBI certain of our patent rights and know-how related to OPT-822/821, a novel carbohydrate-based cancer immunotherapy which we licensed from Memorial Sloan-Kettering Cancer Center. OBI is developing OPT-822/821 for the treatment of metastatic breast cancer. In December 2010, OBI initiated a Phase 2/3 clinical trial of OPT-822/821 with sites in Taiwan, South Korea, Hong Kong and Malaysia. The Phase 2/3 trial is expected to enroll up to 343 patients and the primary endpoint is the progression-free survival rate from the time of randomization until disease progression.

Under the intellectual property assignment and license agreement with OBI, we may receive up to \$10.0 million in milestone payments for each product developed, and we also are eligible to receive royalties on net sales of any product commercialized under the program. In January 2012, OBI and we executed a letter of agreement which provided us the right of first refusal if OBI or one of its affiliates receives any offer to obtain an exclusive, royalty-bearing license (including the right to sublicense) under the OPT-822/821 patents and the OPT-822/821 technology to develop, make, have made, use, sell, offer for sale, have sold and import OPT-

822/821 products in the United States, Europe or other specified territories. In the letter of agreement, as consideration for the grant of the right of first refusal, we waived certain of OBI's obligations under the intellectual property assignment and license agreement. The letter of agreement expires 10 years from the effective date of the agreement.

#### Collaborations, Commercial and License Agreements

AstraZeneca UK Limited. In November 2012, we entered an exclusive distribution and license agreement with AstraZeneca to commercialize fidaxomicin for the treatment of CDI in Latin America, including Brazil, Central America, Mexico and the Caribbean. Under the terms of the agreement, we will provide to AstraZeneca the completed preclinical and clinical data, regulatory information and documents, testing information, protocols and any know-how relating to fidaxomicin. In addition to the transfer of know-how, we will provide drug product for purposes of conducting validation testing in connection with seeking regulatory approval in the covered territories for commercial use of the product. AstraZeneca is obligated to perform, at its own expense, the work required to obtain regulatory approval and commercialization in the covered territories. Under the terms of the agreement, we received a \$1.0 million up-front payment, of which \$0.7 million was recognized in the fourth quarter of 2012, and potentially can earn up to \$3.0 million in aggregate contingent payments, upon first commercial sale in certain countries, and up to \$19.0 million in other contingent payments contingent on the achievement of sales-related targets for fidaxomicin in the territory. In addition, under a fidaxomicin supply agreement with AstraZeneca, we are entitled to receive payments from AstraZeneca that provide a return resulting in a double-digit percent of net sales in the territory.

Specialised Therapeutics Australia Pty. Ltd. In June 2012, we entered into a distribution and license agreement with STA to register and commercialize fidaxomicin in Australia and New Zealand for the treatment of CDI. Under the distribution and license agreement, STA is responsible for all costs associated with the registration and commercialization of fidaxomicin in Australia and New Zealand. In addition, we entered a supply agreement with STA to supply product for the registration and commercial activities of STA and its sublicensees. Upon signing the distribution and license agreement, STA made a payment of \$0.5 million related to expenses incurred by us in connection with pre-approval activities in Australia. We are entitled to receive contingent payments, which may exceed \$1.5 million, upon the achievement of cumulative net sales targets and will receive payments for the supply of fidaxomicin to STA.

Astellas Pharma Inc. In March 2012, we entered into a collaboration and license agreement with Astellas Japan pursuant to which we granted to Astellas Japan an exclusive, royalty-bearing license under certain of our know-how and intellectual property to develop and commercialize fidaxomicin in Japan. Under the terms of the collaboration and license agreement, and at its expense, Astellas Japan agreed to use commercially reasonable efforts to develop and commercialize fidaxomicin in Japan and achieve certain additional regulatory and commercial diligence milestones with respect to fidaxomicin in Japan. In addition, under the terms of the collaboration and license agreement, Astellas Japan granted to us an exclusive, royalty-free license under know-how and intellectual property generated by Astellas Japan and its sublicensees in the course of developing fidaxomicin and controlled by Astellas Japan or its affiliates for use by us and any of our sublicensees in the development and commercialization of fidaxomicin outside Japan and, following termination of the collaboration and license agreement and subject to payment by us of single-digit royalties, in Japan. Under the terms of a supply agreement entered into by Astellas Japan and us, on the same date as the collaboration and license agreement, we are the exclusive supplier of fidaxomicin to Astellas Japan for Astellas Japan's development and commercialization activities in Japan during the term of the supply agreement.

Under the terms of the collaboration and license agreement, Astellas Japan paid us an up-front fee equal to \$20.0 million in April 2012. We also are eligible to receive additional cash payments totaling up to \$70.0 million upon the achievement by Astellas Japan of specified regulatory and commercial milestones. In addition, we will be entitled to receive high-single-digit royalties on net sales of fidaxomicin products in Japan above an agreed threshold, which royalties are subject to reduction in certain limited circumstances. Such royalties will be payable by Astellas Japan on a product-by-product basis until a generic product accounts for a specified market share of the applicable fidaxomicin product in Japan. Under the supply agreement, in exchange for commercial supply of fidaxomicin, Astellas Japan is obligated to pay a price equal to net sales of fidaxomicin products in Japan minus a discount that is based on a high-double-digit percentage of such net sales and a mark-up to cost of goods. This price will be payable by Astellas Japan on a product-by-product basis for commercial supply until a generic product accounts for a specified market share of the applicable fidaxomicin product in Japan.

The collaboration and license agreement will continue in effect on a product-by-product basis until expiration of Astellas Japan's obligation to pay royalties with respect to each fidaxomicin product in Japan, unless terminated early by either party. Following expiration of the collaboration and license agreement, Astellas Japan's license to develop and commercialize the applicable fidaxomicin product will become non-exclusive. Astellas Japan and we may terminate the collaboration and license agreement prior to expiration upon the material breach of such agreement by the other party or upon the bankruptcy or insolvency of the other party. In addition, we may terminate the collaboration and license agreement prior to expiration in the event Astellas Japan, or any of its affiliates or sublicensees, commences an interference or opposition proceeding with respect to, challenges the validity or

enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to, any patent licensed to it under the collaboration and license agreement. Astellas Japan may terminate the collaboration and license agreement prior to expiration for any reason upon 180 days' prior written notice to us. Upon any such termination, the license granted to Astellas Japan (in total or with respect to the terminated product, as applicable) will terminate and revert to us. The supply agreement will continue in effect until terminated by either party. Each of Optimer Europe and Astellas Japan may terminate the supply agreement (i) upon the material breach of such agreement by the other party, (ii) upon the bankruptcy or insolvency of the other party or (iii) on a product-by-product basis following expiration of Astellas Japan's obligation to pay the price described above with respect to the applicable fidaxomicin product, or in its entirety following expiration of Astellas Japan's obligation to pay the price described above with respect to all fidaxomicin products.

Cubist Pharmaceuticals, Inc. On April 5, 2011, we entered into a co-promotion agreement with Cubist, pursuant to which we engaged Cubist as our exclusive partner for the promotion of DIFICID in the United States. Under the terms of the agreement, Cubist and we have agreed to co-promote DIFICID to physicians, hospitals, long-term care facilities and other healthcare institutions as well as jointly to provide medical affairs support for DIFICID. In conducting their respective co-promotion activities, each party is obligated under the agreement to commit minimum levels of personnel, and Cubist is obligated to tie a portion of the incentive compensation paid to its sales representatives to the promotion of DIFICID in the United States. Under the terms of the agreement, we are responsible for the distribution of DIFICID in the United States and for recording revenue from sales of DIFICID, in addition to using commercially reasonable efforts to maintain adequate inventory and third-party logistics support for the supply of DIFICID in the United States. Cubist agreed to not promote competing products in the United States during the term of the agreement and, subject to certain exceptions, for a specified period of time thereafter. The initial term of the agreement will end in July 2013, subject to renewal or early termination as described below. We currently do not anticipate renewing the co-promotion agreement when it expires on July 31, 2013, and will evaluate expanding our field force to detail the hospitals currently covered only by a Cubist representative.

In exchange for Cubist's co-promotion activities and personnel commitments, we are obligated to pay a quarterly fee of approximately \$3.8 million to Cubist (\$15.0 million per year). Cubist also is eligible to receive an additional \$5.0 million in the first year after first commercial sale and \$12.5 million in the second year after first commercial sale if mutually agreed upon annual sales targets are achieved, as well as a portion of our gross profits derived from net sales above the specified annual targets, if any. During 2012, we achieved the first year sales target and expensed \$23.2 million, which consisted of \$14.7 million in quarterly co-promotion fees, \$5.0 million for the year-one sales target bonus and \$3.5 million for Cubist's portion of the gross profit on net sales above the year-one target.

The agreement may be renewed by mutual agreement of the parties for additional, consecutive one-year terms. Cubist and we may terminate the agreement prior to expiration upon the uncured material breach of the agreement by the other party or upon the bankruptcy or insolvency of the other party, subject to certain limitations. In addition, we may terminate the agreement, subject to certain limitations, if (i) we withdraw DIFICID from the market in the United States, (ii) Cubist fails to comply with applicable laws in performing its obligations, (iii) Cubist undergoes a change of control, (iv) certain market events occur related to Cubist's product CUBICIN® (daptomycin for injection) in the United States or (v) Cubist undertakes certain restructuring activities with respect to its sales force. Cubist may terminate the agreement, subject to certain limitations, if (i) we experience certain supply failures in relation to the demand for DIFICID in the United States, (ii) we are acquired by certain types of entities, including competitors of Cubist, (iii) certain market events occur related to CUBICIN in the United States or (iv) we fail to comply with applicable laws in performing our obligations.

Astellas Pharma Europe Ltd. In February 2011, we entered into a collaboration and license agreement with APEL pursuant to which we granted to APEL an exclusive, royalty-bearing license under certain of our know-how and intellectual property to develop and commercialize fidaxomicin in Europe and certain other countries in the Middle East, Africa and the Commonwealth of Independent States, or CIS. In March 2011, APEL and we amended the collaboration and license agreement and the supply agreement (described below) to include certain additional countries in the CIS and all additional territories in Africa (all such countries and territories are referred to as the APEL territory). Under the terms of the collaboration and license agreement, APEL has agreed to use commercially reasonable efforts to develop and commercialize fidaxomicin in the APEL territory at its expense and to achieve certain additional regulatory and commercial diligence milestones with respect to fidaxomicin in the APEL territory. APEL and we also may agree to collaborate in, and share data resulting from, global development activities with respect to fidaxomicin, in which case we and APEL will be obligated to co-fund such activities. In addition, under the terms of the collaboration and license agreement, APEL granted us an exclusive, royalty-free license under know-how and intellectual property generated by APEL and its sublicensees in the course of developing fidaxomicin and controlled by APEL or its affiliates for use by us and any of our sublicensees in the development and commercialization of fidaxomicin outside the APEL territory and, following termination of the agreement and subject to payment by us of single-digit royalties, in the APEL territory. Under the terms of a supply agreement entered into between APEL and us, on the same date, we will be the exclusive supplier of fidaxomicin to APEL for APEL's development and commercialization activities in the APEL territory during the term of the supply agreement, and APEL is obligated to pay us an amount equal to cost plus an agreed mark-up for such supply.

Under the terms of the collaboration and license agreement, in March 2011, APEL paid us an up-front fee of \$69.2 million. In June 2012, APEL paid us 50.0 million Euros, which consisted of a 40.0 million Euro approval milestone payment and a 10.0 million Euro milestone payment for the first commercial launch of DIFICLIR in an APEL territory. We are eligible to receive additional milestone payments totaling up to 65.0 million Euros upon the achievement of specified commercial milestones.

In addition, we are entitled to receive escalating double-digit royalties ranging from the high teens to low twenties on net sales of fidaxomicin products in the APEL territory, which royalties are subject to reduction in certain, limited circumstances. These royalties are payable by APEL on a product-by-product and country-by-country basis until a generic product accounts for a specified market share of the applicable fidaxomicin product in the applicable country.

The agreements with APEL will continue in effect on a product-by-product and country-by-country basis until expiration of APEL's obligation to pay royalties with respect to each fidaxomicin product in each country in the APEL territory, unless terminated early by either party as more fully described below. Following expiration, APEL's license to develop and commercialize the applicable fidaxomicin product in the applicable country will become non-exclusive. APEL and we may each terminate either of the agreements, prior to expiration, upon the material breach of such agreement by the other party or upon the bankruptcy or insolvency of the other party. In addition, we may terminate the agreements prior to expiration in the event APEL, or any of its affiliates or sublicensees, commences an interference or opposition proceeding with respect to, challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to, any patent licensed to it. APEL may terminate the agreements prior to expiration for any reason on a product-by-product and country-by-country basis upon 180 days' prior written notice to us. Upon any such termination, the license granted to APEL (in total or with respect to the terminated product or terminated country, as applicable) will terminate and revert to us.

Par Pharmaceutical, Inc. In February 2007, we repurchased the rights to develop and commercialize fidaxomicin in North America and Israel from Par under a prospective buy-back agreement. We paid Par a \$5.0 million milestone payment in June 2010 for the successful completion of our second pivotal Phase 3 trial for fidaxomicin. We are obligated to pay Par a 5% royalty on any net sales by us, our affiliates or our licensees of fidaxomicin in North America and Israel, including Cubist, and a 1.5% royalty on any net sales by us or our affiliates of fidaxomicin in the rest of the world. In addition, we are required to pay Par a 6.25% royalty on net revenues we receive related to fidaxomicin in connection with the licensing of our right to market fidaxomicin in the rest of the world, such as the licenses we have granted to our partners in territories outside the United States and Canada. 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.

Biocon Limited. In May 2010, we entered into a long-term supply agreement with Biocon for the commercial manufacture of fidaxomicin active pharmaceutical ingredient, or API. Pursuant to the agreement, Biocon agreed to manufacture and supply, up to certain limits, fidaxomicin API and, subject to certain conditions, we agreed to purchase from Biocon at least a portion of our requirements for fidaxomicin API in the United States and Canada. We previously paid to Biocon \$2.5 million for certain equipment purchases and manufacturing scale-up activities, and we may be entitled to recover up to \$1.5 million of this amount under the supply agreement in the form of discounted prices for fidaxomicin API. As of December 31, 2012, we had recovered approximately \$0.9 million of the \$1.5 million. Unless both Biocon and we agree to extend the term of the supply agreement, it will terminate in November 2018. The supply agreement may be earlier terminated (i) by either party by giving two and one-half years' notice after the fifth anniversary of the effective date or upon a material breach of the supply agreement by the other party, (ii) by us upon the occurrence of certain events, including Biocon's failure to supply requested amounts of fidaxomicin API or (iii) by Biocon upon the occurrence of certain events, including our failure to purchase amounts of fidaxomicin API indicated in binding forecasts.

Patheon Inc. In June 2011, we entered into a commercial manufacturing services agreement with Patheon Inc., or Patheon, to manufacture and supply fidaxomicin drug product in North America, Europe and other countries, subject to agreement by the parties to any additional fees for such countries. We agreed to purchase a specified percentage of our fidaxomicin product requirements for North America and Europe from Patheon or its affiliates.

The term of the agreement extends through December 31, 2016 and automatically will renew for subsequent two-year terms unless either party provides a timely notice of its intent not to renew or unless the agreement is terminated early pursuant to its terms. Patheon and we may terminate the agreement prior to expiration upon the uncured material breach of the agreement by the other party or upon the bankruptcy or insolvency of the other party. In addition, the agreement will terminate with respect to any fidaxomicin product if we provide notice to Patheon that we no longer require manufacturing services for such product because the product has been discontinued. We may terminate the agreement, subject to certain limitations, (i) with respect to any fidaxomicin product if any regulatory authority takes any action or raises any objection that prevents us from importing, exporting, purchasing or selling such product, or if we determine to discontinue development or commercialization of such product for safety or efficacy reasons, (ii) if any regulatory authority takes an enforcement action against Patheon's manufacturing site that relates to fidaxomicin products or that

could reasonably be expected to adversely affect Patheon's ability to supply fidaxomicin products to us, (iii) if Patheon is unable to deliver or supply any firm orders for any two calendar quarters during any four consecutive calendar quarters, (iv) if Patheon uses any debarred or suspended person in the performance of its service obligations under the agreement or (v) if Patheon fails to meet certain production yield requirements.

Cempra, Inc. In March 2006, we entered into a collaborative research and development and license agreement with Cempra. We granted to Cempra an exclusive worldwide license, except in the Association of Southeast Asian Nations, or ASEAN, with the right to sublicense our patents and know-how related to our macrolide and ketolide antibacterial program. As partial consideration for granting Cempra the license, we obtained equity of Cempra representing an ownership interest of less than 20%. We may 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 milestone payments will be triggered upon the completion of certain clinical development milestones and, in certain instances, regulatory approval of products. We also may receive royalty payments based on a percentage of net sales of licensed products.

Pursuant to the agreement, Cempra granted us an exclusive license whereby Cempra may receive milestone payments from us in the amount of \$1.0 million 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.

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 also may 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 will survive upon the express election of the non-terminating party.

In June 2012, Cempra completed its first Phase 2 clinical trial of solithromycin (CEM101) in patients with community-acquired bacterial pneumonia, which triggered a \$1.0 million milestone payment to us. To date, we have received \$1.5 million in payments from this collaboration.

OBI. In October 2009, we entered into certain transactions involving OBI, our then wholly-owned subsidiary, to provide funding for the development of two of our early-stage, non-core programs. The transactions with OBI included an intellectual property assignment and license agreement, pursuant to which we assigned to OBI certain patent rights, information and know-how related to OPT-822/821. In anticipation of these transactions, we assigned, and OBI assumed, our rights and obligations under related license agreements with the Memorial Sloan-Kettering Cancer Center. Under the intellectual property assignment and license agreement, we are eligible to receive up to \$10.0 million in milestone payments related to the development of OPT-822-821, and we are eligible to receive royalties on net sales of any product which is commercialized under the program. The term of the intellectual property assignment and license agreement continues until the last to expire of the patents assigned by us to OBI and the patents licensed to OBI.

In January 2012, OBI and we executed a letter of agreement which provided us the right of first refusal if OBI or one of its affiliates receives any offer to obtain an exclusive, royalty-bearing license (including the right to sublicense) under the OPT-822/821 patents and the OBI OPT-822/821 technology to develop, make, have made, use, sell, offer for sale, have sold and import OPT-822/821 products in the United States, Europe or other specified territories. In the letter of agreement, as consideration for the grant of the right of first refusal, we waived certain of OBI's obligations under the intellectual property assignment and license agreement. The letter of agreement expires 10 years from the effective date of the agreement.

In the fourth quarter of 2012, we sold our remaining ownership interest in OBI for \$60.0 million in gross proceeds, but retain our rights to receive milestone and royalty payments related to OPT-822/821 under the intellectual property assignment and license agreement. We also retain a right of first refusal to license commercial rights to OPT-822/821 in the United States, Europe or other specified territories.

The Scripps Research Institute. In July 1999, we acquired exclusive, worldwide rights to certain drug development technology from The Scripps Research Institute, or TSRI. The agreement with TSRI includes the license to us of patents, patent applications and copyrights related to the 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 and carbohydrate mimetics.

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. In October 2009, we assigned to OBI one of the agreements with TSRI related to OPT-88 which, after further evaluation, OBI decided not to pursue. In February 2011, the license agreement related to OPT-88 was terminated and OBI returned the patents related to OPT-88. Under each of the three remaining agreements, 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 three agreements, we will owe TSRI payments upon achievement of certain milestones. In two of the three TSRI agreements, the milestones are the successful completion of a Phase 2 trial or its foreign equivalent, the submission 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 clinical trial or its foreign equivalent, the submission 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 the remaining TSRI agreements is approximately \$11.1 million. We currently are not developing any products covered by the TSRI agreements.

### Manufacturing

We rely on third parties to manufacture fidaxomicin and currently have no plans to develop our own commercial manufacturing capability. We require in our manufacturing and processing agreements that all third-party contract manufacturers and processors produce fidaxomicin API and finished products in accordance with current Good Manufacturing Practices, or 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 fidaxomicin.

In May 2010, we entered into a long-term supply agreement with Biocon for the commercial manufacture of fidaxomicin API. In June 2011, we entered into a commercial manufacturing services agreement with Patheon to manufacture fidaxomicin drug products, including DIFICID. The manufacturing facilities of Biocon and Patheon have been approved by the FDA for the manufacture of our fidaxomicin drug supplies. We may contract with other third-party contract manufacturers for additional commercial supply of fidaxomicin API and fidaxomicin drug product for commercial sale.

#### **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 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 (see "Risk Factors — Risks Related to Our Intellectual Property").

With respect to fidaxomicin, we have five issued U.S. patents and 16 U.S. pending patent applications. We also have 25 issued foreign patents and 77 pending foreign counterparts in Australia, Canada, China, Europe, Hong Kong, Israel, Japan, South Korea, India, New Zealand, Taiwan, South Africa, Russian Federation, Mexico, Brazil, Chile, Colombia and Peru. The issued patents cover a specific polymorphic form, methods of treatment and specific manufacturing methods and expire in 2027, 2027 and 2025, respectively. The pending patent applications, if issued, may cover the composition of matter, an additional polymorphic form, and pharmaceutical formulations containing the various components and would expire between 2023 and 2029.

#### **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. All of our product candidates will require regulatory approval by governmental agencies prior to commercialization. In particular, pharmaceutical products are subject to rigorous preclinical testing and clinical trials and other pre-marketing 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 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 preclinical studies. Preclinical testing includes both *in vitro* and *in vivo* laboratory evaluation and characterization of the safety and efficacy of a drug and its formulation. Preclinical 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 preclinical data must provide an adequate basis for evaluating both the safety and the scientific rationale for the initial trials in healthy volunteers. In order to test a new drug in humans in the United States, an IND must be submitted to the FDA. The IND will become effective automatically 30 days after receipt by the FDA, unless the FDA raises concern or questions significant enough to merit a clinical hold, in which case the IND sponsor and the FDA must resolve any outstanding concerns before a hold is lifted and 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. Certain clinical trials are required to be publicly registered, as with www.clinicaltrials.gov, and their results made publicly available.

- Phase 1. Phase 1 human clinical trials evaluate the safety profile of a product candidate 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 subjects to evaluate its pharmacokinetic properties, safety, dose range and side effects. We also may 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 typically are designed to evaluate the potential effectiveness of the product candidate 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 also may 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 or registration clinical trials, the product candidate 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 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. Trials designed to register potential new indications for approved products are called Phase 3b.
- Phase 4. Phase 4 clinical trials include 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. Failure to promptly conduct any mandatory Phase 4 clinical trials that are required to as part of an NDA approval could result in withdrawal of approval or other legal sanction.

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 preclinical 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 often is 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 a complete response, the latter of which usually contains a number of conditions that must be satisfied in order to secure final approval.

### FDA Post-approval Process

Even after approval of an NDA, such approval is subject to a wide-range of regulatory requirements, any or all of which may adversely impact a sponsor's ability to effectively market and sell the approved product. Furthermore, the FDA may require the sponsor to conduct non-clinical and/or additional clinical trials, also known as post-marketing requirements or post-marketing commitments, to provide additional information on the safety and efficacy of the approved product. The results of such post-market studies may be negative and could lead to limitations on the further marketing of a product. Also, under the Pediatric Research Equity Act, or PREA, the FDA may require pediatric assessment of certain drugs and, if the results of these studies are negative, marketing of the product in adults could be impacted. In addition, the FDA may require a sponsor to implement a Risk Evaluation Mitigation Strategy, or REMS, to manage a known or potential serious risk associated with the product. The FDA may, either prior to approval or subsequent to approval if new safety data arises, require a REMS if it determines that a REMS is necessary to ensure that the benefits of the product outweigh its risks. Failure to comply with a REMS, including submission of a required assessment, may result in substantial civil penalties.

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 cGMP regulations which impose procedural and documentation requirements upon us and any third-party manufacturers we utilize. Significant negative findings in such an inspection could impact our ability to supply our products. In December 2012, the FDA conducted an unannounced, routine inspection of Drug Safety and Pharmacovigilance at our facility in Jersey City, New Jersey. The primary purpose of the inspection was to review all systems, procedures, documentation and any adverse event reports associated with fidaxomicin usage. The inspection lasted five days and concluded with no observations and no Forms 483.

The FDA closely regulates the marketing and promotion of drugs. A company can make only those claims relating to safety and efficacy that are part of, or consistent with, the FDA-approved product labeling. 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 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 and healthcare payors, including the federal government, can use the False Claims Act and related statutes to pursue drug companies for off-label promotion that results in the submission of claims for payment for uses that have not been approved by the FDA as safe and effective.

The FDA requires a sponsor to submit reports of certain information on side effects and adverse events associated with its products that occur either during clinical trials or after marketing approval. These requirements include specific and timely notification of certain serious, unexpected and/or frequent adverse events, as well as regular periodic reports summarizing adverse drug experiences. Failure to comply with these FDA safety reporting requirements may result in FDA regulatory action that may include civil action or criminal penalties. In addition, as a result of these reports, the FDA could create a Tracked Safety Issue for a product in the FDA's Document Archiving, Reporting and Regulatory Tracking System, place additional limitations on an approved product's use, such as through labeling changes, or, potentially, could require withdrawal or suspension of the product from the market.

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.

Our marketing partners and we are subject to a wide variety of foreign regulatory requirements as we commercialize fidaxomicin internationally. Approval of a drug by applicable regulatory agencies of foreign countries must be secured prior to the marketing of such drug in those countries. The regulatory approval process in countries outside of the United States vary widely from country to country and may, in some cases, be more rigorous than requirements in the United States. Certain foreign regulatory authorities may require additional studies or studies designed with different clinical endpoints and/or comparators than those which we are conducting or have already completed. In addition, any adverse regulatory action taken by the FDA with respect to an approved product in the United States may affect the regulatory requirements or decisions made by certain foreign regulatory bodies with regard to the regulatory approval of products outside of the United States.

We are 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 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.

### 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 diseases. 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 already have established themselves in the markets for the treatment of CDAD and many additional companies currently are developing products for the treatment of CDAD, which we expect will compete with fidaxomicin if approved for marketing. Potentially significant competitors to fidaxomicin both currently marketed and that have completed Phase 2 clinical development, include the following:

Product	Stage of Development	Company
Flagyl™/metronidazole	Marketed	Pfizer, Sanofi-Aventis and generics
Vancocin/oral vancomycin	Marketed	Viropharma and generics
Ramoplanin	Phase 2 completed	Nanotherapeutics
MK-3415/MK-6072/MK-3415A (antibodies combination)	Phase 3	Merck
CB-315	Phase 3	Cubist
Cadazoloid	Phase 2 completed	Actelion

#### **Research and Development**

Our research and development efforts primarily are focused on further developing fidaxomicin for additional indications and expansion of the label. Our research and development expense was approximately \$45.2 million, \$43.1 million and \$32.8 million in years 2012, 2011 and 2010, respectively.

#### **Employees**

As of February 15, 2013, we employed 281 persons, of which 138 are in commercial operations, including 116 in sales. Additionally, 87 are in clinical research, regulatory affairs, health economics and medical affairs and manufacturing. Fifty-six are in corporate administration, including finance, legal, access, 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.

#### **Geographic Information**

#### Revenues

Information regarding our revenues by geographic area since we began sales in 2011 is as follows:

	December 31,					
		2012 2011				
	(in thousands)					
United States	\$	61,991	\$	21,511		
Ex - United States		39,538		122,749		
	\$	101,529	\$	144,260		

Does not include grant revenues.

#### Long-lived Assets

Information regarding our long-lived assets by geographic area is as follows:

	,	Dec	ember 31,		
2012		2011		2010	
		(in thousands)			
\$	4,237	\$	2,358	\$	590
	52		_		
			233		108
\$	4,289	\$	2,591	\$	698
	\$ \$	\$ 4,237 52	\$ 4,237 \$ (in t)	\$ 4,237 \$ 2,358 52 — 233	2012   2011   (in thousands)

#### Item 1A. Risk Factors

#### Risks Related to Our Business

#### Our success largely depends on our ability to successfully commercialize our only product, DIFICID.

Our success depends on our ability to effectively commercialize our only product, DIFICID, which was approved by the FDA in May 2011 for the treatment of CDAD in adults 18 years of age and older. We launched DIFICID in the United States in July 2011 and launched DIFICID in Canada in June 2012 following our receipt of Canadian marketing approval. Our ability to effectively commercialize and generate revenues from DIFICID will depend on several factors, including:

- our continued ability to create market demand in the United States for DIFICID through our own commercial activities as well as through our co-promotion agreement with Cubist;
- our ability to successfully implement customer contracting and discounting programs to certain institutional customer segments, such as hospitals and group purchasing organizations;
- the effectiveness of our reimbursement support programs designed to improve patient access to DIFICID;
- the ability of our collaboration partners to successfully commercialize fidaxomicin outside the United States and Canada;
- our continued ability to train, deploy and support a qualified sales force;
- our continued ability to preserve existing formulary acceptance and secure additional formulary approvals for DIFICID at a substantial number of targeted hospitals and long-term care facilities;
- the availability of adequate coverage or reimbursement for DIFICID by government healthcare programs and third-party payors, including private health coverage insurers and health maintenance organizations;
- our customers' ability to realize adequate reimbursement from payors, including CMS's recently implemented New Technology Add-on Payment, or NTAP, program for DIFICID
- the performance of our third-party manufacturers and our ability to ensure that our supply chain efficiently and consistently delivers DIFICID to our customers and collaboration partners;
- our ability to implement and maintain agreements with wholesalers and distributors on commercially reasonable terms;
- our ability to expand the label of DIFICID to cover additional indications; and
- our ability to maintain and defend our patent protection and regulatory exclusivity for DIFICID.

Any disruption in our ability to generate revenues from the sale of DIFICID or lack of success in its commercialization will have a substantial adverse impact on our results of operations.

The success of our efforts to commercialize DIFICID in the United States will be partially dependent on our co-promotion agreement with Cubist.

Pursuant to our co-promotion agreement with Cubist, we engaged Cubist as our exclusive partner for the promotion of DIFICID in the United States. The initial term of the agreement will end in July 2013, subject to potential renewal for additional one-year terms. We have limited control over the amount and timing of resources that Cubist may devote to the co-promotion of DIFICID. If Cubist fails to adequately promote DIFICID, or if Cubist's efforts are not effective for any other reason, our business may be negatively affected. In particular, we are relying on our co-promotion agreement with Cubist to reach a broader segment of the CDAD market than we currently can reach on our own. If Cubist is unsuccessful or the co-promotion agreement is terminated earlier than we expect, we may not be able to address these broader CDAD market segments, and the revenues we may generate from sales of DIFICID in the United States will be limited.

We are subject to a number of other risks associated with our dependence on our co-promotion agreement with Cubist, including:

- Cubist could fail to devote sufficient resources to the promotion of DIFICID, including by failing to maintain or train sufficient sales or medical affairs personnel to promote or provide information regarding DIFICID;
- Cubist may not provide us with timely and accurate information regarding promotion and sales activities with respect to DIFICID, which could adversely impact our ability to manage our own inventory of DIFICID in the United States, as well as our ability to generate accurate financial forecasts;
- Cubist and we may not be successful in coordinating our respective sales and promotion activities under the co-promotion agreement, which could lead to inefficiencies, the failure to maximize DIFICID sales in the Unites States, and/or disagreements between Cubist and us;
- Cubist may not comply with applicable regulatory guidelines with respect to the promotion of DIFICID, which could adversely impact sales of DIFICID in the United States; or
- business combinations or significant changes in Cubist's business strategy, including the acquisition or development by Cubist of other products, may adversely affect Cubist's ability or willingness to perform its obligations under our copromotion agreement.

Our co-promotion agreement with Cubist is subject to early termination, including through Cubist's right to terminate if we experience certain supply failures in relation to the demand for DIFICID in the United States or if we are acquired by certain types of entities, including competitors of Cubist. If the agreement is terminated early, we may not be able to find another partner to co-promote DIFICID in the United States on acceptable terms, or at all, and we may be unable to sufficiently promote and commercialize DIFICID in the United States on our own. If the agreement is not renewed beyond July 2013, we may be unable to successfully replace the resources and efforts of Cubist in co-promoting DIFICID and our sales of DIFICID in the United States may decline as a result. We currently do not anticipate renewing the co-promotion agreement when it expires on July 31, 2013, and will evaluate expanding our field force to detail the hospitals currently covered only by a Cubist representative.

We are dependent on our collaboration agreements with various third parties to commercialize and further develop fidaxomicin in territories outside the United States and Canada. The failure to maintain these agreements or the failure of our collaboration partners to perform their obligations under their respective agreements, could negatively impact our business.

Pursuant to the terms of our collaboration agreements, we granted to third parties, including APEL, Astellas Japan, STA and AstraZeneca, exclusive rights to develop and commercialize fidaxomicin in various territories outside the United States and Canada, including Europe, Japan, Australia and Latin America. We also have entered into supply agreements with our collaboration partners pursuant to which we are obligated to supply our partners all of their requirements of fidaxomicin for such development and commercialization activities. Consequently, our ability to generate any revenues from fidaxomicin in territories outside the United States and Canada depends on our collaboration partners' ability to obtain regulatory approvals for and successfully commercialize fidaxomicin in their respective territories. We have limited control over the amount and timing of resources that our collaboration partners will dedicate to these efforts.

We are subject to a number of other risks associated with our dependence on our collaboration agreements including:

- our collaboration partners may not comply with applicable regulatory guidelines with respect to developing or commercializing fidaxomicin, which could adversely impact sales or future development of fidaxomicin outside the United States and Canada;
- our collaboration partners could disagree as to future development plans and our collaboration partners may delay future clinical trials or stop a future clinical trial;
- there may be disputes between our collaboration partners and us, including disagreements regarding the applicable collaboration agreement, that may result in (i) the delay of or failure to achieve regulatory and commercial objectives that would result in milestone or royalty payments, (ii) the delay or termination of any future development or commercialization of fidaxomicin and/or (iii) costly litigation or arbitration that diverts our management's attention and resources;
- because the milestone and royalty payments in the collaboration agreement with APEL are stated in terms of Euros but paid to us in U.S. Dollars, the amounts of any milestone or royalty payments that may be paid to us under the collaboration agreement could be less than what we expect, depending on the applicable exchange rate at the time of such payments;
- our collaboration partners may not provide us with timely and accurate information regarding sales and marketing activities and supply forecasts, which could adversely impact our ability to comply with our supply obligations to our collaboration partners and manage our own inventory of fidaxomicin, as well as our ability to generate accurate financial forecasts;
- business combinations or significant changes in our collaboration partners' business strategy may adversely affect our
  collaboration partners' ability or willingness to perform their respective obligations under our collaboration and supply
  agreements;
- our collaboration partners may not properly maintain or defend our intellectual property rights in the their respective territories or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential litigation;
- the payments we are eligible to receive from our collaboration partners may be reduced or eliminated based upon our collaboration partners' and our ability to maintain or defend our intellectual property rights and the presence of generic competitors in the applicable territories;
- limitations under certain of our collaboration agreements on our, or an acquiror's, ability to maintain or pursue development or commercialization of products that are competitive with fidaxomicin could deter a potential acquisition of us that our stockholders may otherwise view as beneficial; and
- if our collaboration partners are unsuccessful in obtaining regulatory approvals for or commercializing fidaxomic in in the their respective territories, we may not receive any payments under the applicable collaboration agreement and our business prospects and financial results may be materially harmed.

Our collaboration and supply agreements are subject to early termination, including through our collaboration partners' right to terminate without cause upon advance notice to us. If the agreements are terminated early, we may not be able to find another collaborator for the commercialization and further development of fidaxomicin in the applicable territory on acceptable terms, or at all, and we may be unable to pursue continued commercialization or development of fidaxomicin in the applicable territory on our own.

We may enter into additional agreements for the commercialization of fidaxomicin and may similarly be dependent on the performance of third parties with similar risk.

Other than our existing collaboration agreements, we may not be able to enter into acceptable agreements to commercialize fidaxomicin outside of the United States and Canada or, if needed, adequately build our own marketing and sales capabilities.

We intend to continue the development and commercialization of fidaxomicin outside of the United States and Canada through collaboration arrangements with third parties, such as our collaborations with APEL, Astellas Japan, STA and AstraZeneca, or independently. We may be unable to enter into additional collaboration arrangements in international markets. In addition, there can be no guarantee that our existing collaboration partners or any other parties with which we may enter into collaboration arrangements will be successful or will generate more revenues than we could obtain by marketing fidaxomicin on our own. If we are

unable to enter into additional 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 additional collaboration arrangements for development of fidaxomicin in countries outside of the United States and Canada, or if we otherwise decide to market fidaxomicin ourselves in these countries, we will need to develop our own marketing and sales force to market fidaxomicin to hospital-based and long-term care physicians in these territories. These efforts may not be successful as we have limited relationships among such hospital-based and long-term care physicians and may not currently have sufficient funds to develop an adequate sales force in each of these regions. If we cannot commercialize fidaxomicin, either through a collaboration or independently, in any territory that represents a significant market opportunity, our ability to achieve and sustain profitability will be substantially limited.

## 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, 2012, we had an accumulated deficit of approximately \$252.0 million. We have generated limited revenues from product sales and collaborations to date, and we expect our expenses to continue to be significant in the near-term as we execute the commercialization of DIFICID due to, among other things, our employee headcount, on-going payments to Cubist pursuant to our co-promotion agreement and our pursuit of additional research and development activities, including potential additional indications and life-cycle management projects for DIFICID. We have funded our operations through December 31, 2012 primarily from the sale of approximately \$333.8 million of our equity securities and through payments received under collaborations with partners or government grants and product revenues from sales of DIFICID. Because of the numerous risks and uncertainties associated with commercializing DIFICID and with developing, obtaining regulatory approval for and commercializing any future product candidates, we are unable to predict the extent of any future losses. Our collaborators or we may never successfully commercialize our products or product candidates, including fidaxomicin outside of the United States, and thus we may never have any significant future revenues or achieve and sustain profitability.

## The commercial success of DIFICID, and any other products we develop or acquire, will depend upon attaining significant market acceptance among physicians, hospitals, patients, healthcare payors and the medical community.

Even after being approved by the appropriate regulatory authorities for marketing and sale, physicians may not prescribe any of our products, which would prevent us from generating revenues or becoming profitable. Market acceptance of our products by physicians, hospitals, patients and healthcare payors generally will depend on a number of factors, many of which are beyond our control, including:

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

With respect to DIFICID specifically, successful commercialization will depend on whether, and to what extent, physicians, pharmacists, long-term care facilities and hospital pharmacies, over whom we have no control, determine to utilize DIFICID. The sale of DIFICID to each hospital is, to a large extent, dependent upon the addition of DIFICID to that hospital's list of approved drugs, or formulary, and we may experience substantial delays in obtaining formulary approvals and restrictions on the usage of the drug may be implemented. We cannot guarantee that we will be successful in getting additional approvals in a timely manner or at all, and the failure to do so will limit our ability to optimize hospital sales of DIFICID.

Even if we obtain hospital formulary approval for DIFICID, physicians must still prescribe DIFICID for its commercialization to be successful. Because DIFICID is a new drug with a limited track record of sales in the United States, any inability to timely supply DIFICID to our customers, or any unexpected side effects that arise from the use of the drug may lead physicians to not accept DIFICID as a viable treatment alternative.

Even after receipt of regulatory approval from the FDA, DIFICID is, and any other products we may develop or acquire in the future will be, subject to substantial, ongoing regulatory requirements.

DIFICID is, and any future approved products will be, subject to ongoing FDA requirements with respect to manufacturing, labeling, packaging, storage, distribution, advertising, promotion, record-keeping and submission of safety and other post-market information on the drug. The FDA has the authority to regulate the claims we make in marketing any products, including DIFICID, to ensure that such claims are true, not misleading, supported by scientific evidence and consistent with the approved label for the drug. In addition, the discovery of previously unknown problems with DIFICID or any future approved product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where active pharmaceutical ingredient, or API, or final drug product is manufactured, may result in the imposition of additional restrictions, including requiring us to reformulate the product, conduct additional clinical trials, make changes in the labeling of the product or withdraw the product from the market.

The FDA or foreign regulatory authorities also may impose ongoing requirements for potentially costly post-approval studies for any approved product. For example, as a condition of the FDA's approval of DIFICID, we are required to conduct a microbiological surveillance program to identify the potential for decreased susceptibility of *C. difficile* to DIFICID, as well as two post-marketing studies in pediatric patients and a randomized trial to evaluate the efficacy of DIFICID in the treatment of patients with multiple CDAD recurrences. Depending on the outcome of the studies, we may be unable to expand the indications for DIFICID, or we may be required to include specific warnings or limitations on dosing this product, which could negatively impact our sales of DIFICID.

We have implemented a comprehensive compliance program and related infrastructure, but we cannot provide absolute assurance that we are or will be in compliance with all potentially applicable laws and regulations. If our operations, in relation to DIFICID or any future approved product, fail to comply with applicable regulatory requirements, the FDA or other regulatory agencies may:

- issue warning letters or untitled letters;
- impose consent decrees, which may include the imposition of various fines, reimbursement for inspection costs, due dates for specific actions and penalties for noncompliance;
- impose fines or other civil or criminal penalties;
- suspend regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on operations, including costly new manufacturing requirements;
- exclude us from participating in U.S. federal healthcare programs, including Medicaid or Medicare; or
- seize or detain products or require a product recall.

Any of these regulatory actions, due to our failure to comply with post-approval requirements, could damage our reputation, limit our ability to market our products and adversely affect our operating results. In addition, the failure of our current or future collaborators to comply with these regulations and similar regulations in foreign jurisdictions would limit our ability to fully commercialize fidaxomicin and any other product we may develop or acquire in the future.

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.

In the United States, in addition to FDA restrictions, we are subject to healthcare fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal healthcare programs' Anti-Kickback Law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal laws that prohibit executing a scheme to defraud any health care benefit program or making false statements relating to health care matters;
- federal "sunshine" laws that require transparency regarding financial arrangements with health care providers, such as the reporting and disclosure requirements imposed by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, the PPACA, on drug manufacturers regarding any "transfer of value" made or distributed to prescribers and other health care providers; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Some states, such as California, Massachusetts and Vermont, mandate implementation of comprehensive compliance programs to ensure compliance with these laws.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by applicable regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn are used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, also violate false claims laws.

Recent healthcare reform legislation has strengthened these laws. For example, the recently enacted PPACA, among other things, amended the intent requirement of the federal anti-kickback and criminal health care fraud statutes such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. We expect there will continue to be federal and state laws and/or regulations, proposed and implemented, that could impact our operations and business. The extent to which future legislation or regulations, if any, relating to healthcare fraud abuse laws and/or enforcement, may be enacted or what effect such legislation or regulation would have on our business remains uncertain.

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 these laws, and we increased our compliance resources in connection with the commercial launch of DIFICID. However, because of the far-reaching nature of these laws, there can be no

assurance that we will 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 product sales depend on adequate coverage and reimbursement from third-party payors.

Sales of DIFICID by our collaborators and us are dependent on the availability and extent of coverage and reimbursement from third-party payors, including government healthcare programs and private insurance plans, as well as effective use by our customers of reimbursement programs for DIFICID. Our collaborators and we rely in large part on the reimbursement coverage by federal and state sponsored government programs, such as Medicare and Medicaid in the United States, which are increasingly challenging prices charged and the cost-effectiveness of medical products. These practices may be further exacerbated by future healthcare reform measures. In addition, many healthcare providers, such as hospitals, receive a fixed reimbursement amount per procedure or other treatment therapy based on a prospective payment system, and these amounts are not necessarily based on the actual costs incurred. As a result, these healthcare providers may be inclined to choose the least expensive therapies. We cannot guarantee that our potential customers will find the reimbursement amounts sufficient to cover the costs of our products, including DIFICID.

We have licensed rights to develop and commercialize fidaxomicin in Europe, Japan, Australia, Latin America and certain other territories to our collaboration partners. In the event our collaborators or we seek approvals to market fidaxomicin in other non-U.S. territories, our collaborators or we will need to work with the applicable government-sponsored healthcare entities in the applicable territories that are the primary payors of healthcare costs in such regions. Certain government payors may regulate prices, reimbursement levels and/or access to fidaxomicin or any future products to control costs or to affect levels of use of the product.

We cannot predict the availability or level of coverage and reimbursement for DIFICID or any future approved product. If third-party coverage and reimbursement is not available, or is available only to limited levels, we may not be able to commercialize DIFICID or any other products successfully or at all, which would materially harm our business and prospects.

Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated as listed in the approved labeling.

Any regulatory approval is limited to those specific diseases and indications for which a product is deemed to be safe and effective by the FDA. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval.

While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote the products is limited to those indications that are specifically approved by the FDA. Regulatory authorities in the United States generally do not regulate the behavior of physicians in their choice of treatments, and such off-label uses by healthcare professionals are common. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. If we are not able to obtain FDA approval for any desired future indications for DIFICID or any future approved products, our ability to market and sell such products will be limited and our business may be adversely affected.

If our collaborators or we fail to gain and/or maintain marketing approvals from regulatory authorities in international markets for fidaxomicin and any future product candidates for which we have or license rights in any significant international markets, our market opportunities will be limited.

The ability of our collaborators and us to sell our product candidates outside of the United States is 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 also must approve the marketing of the product candidate in those countries. 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 guarantee regulatory approval will be obtained in any other country. In addition, our collaborators' or our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in others. We could experience significant delays and difficulties and incur significant costs in obtaining foreign regulatory approvals in the territories for which we retain commercialization rights.

Other than DIFICLIR's approval by the EMA in Europe and DIFICID's approval in Canada, none of our product candidates is approved for sale in any significant international market. If our collaborators or we fail to comply with regulatory requirements with

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

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

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

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

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

We have product liability insurance that covers our commercial product as well as global clinical trial liability insurance. Our current or future insurance coverage may prove insufficient to cover any liability claims brought against us. 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.

# If we fail to obtain additional financing, we may be unable to commercialize DIFICID and develop and commercialize other product candidates.

We may require additional capital to fully commercialize DIFICID and any future products for which we obtain regulatory approval or acquire or in-license. 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 scale back our commercialization activities for DIFICID in the United States and Canada or significantly delay, scale back or discontinue the development of one or more of our product candidates or research and development initiatives.

To the extent we require additional resources to successfully commercialize DIFICID, and we are unable to raise additional capital or are unable to effectively collaborate with additional partners for the commercialization of DIFICID, we will not generate significant revenues from sales of this product, and our business will be harmed materially.

## If we fail to attract and retain senior management and key personnel, we may be unable to successfully develop or commercialize our product candidates.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, sales and marketing, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. Since the beginning of 2012, there have been several changes to our senior management team including the appointment of a new chief executive officer, chief financial officer, and general counsel and chief compliance officer, among others. The unexpected loss of the service of any of these new appointees or their failure to perform as expected may significantly delay or prevent the achievement of research, development, commercialization and other business objectives. 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 pharmaceutical 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 may not be able to attract or retain qualified management, sales and marketing 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 and New Jersey areas. 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 commercialization and 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.

As a result of ongoing investigations by U.S. authorities, it is possible that we and certain of our current and former employees and directors may be named as defendants in future civil or criminal enforcement proceedings that could result in substantial penalties and costs, and divert management's attention.

In March 2012, we became aware of an attempted grant in September 2011 to Dr. Michael Chang of 1.5 million technical shares of OBI. We engaged external counsel to assist us in an internal review and determined that the attempted grant may have violated certain applicable laws, including the Foreign Corrupt Practices Act, or the FCPA.

In April 2012, we self-reported the results of our preliminary findings to the SEC and the U.S. Department of Justice, or the DOJ, which included information about the attempted grant and certain related matters, including a potentially improper \$300,000 payment in July 2011 to a research laboratory involving an individual associated with the OBI share grant. At that time, we terminated the employment of our then-Chief Financial Officer and our then-Vice President, Clinical Development. We also removed Dr. Michael Chang as the Chairman of our Board of Directors and requested that Dr. Michael Chang resign from the Board of Directors, which he has not. We continued our investigation and our cooperation with the SEC and the DOJ.

As a result of our continuing internal investigation, in February 2013, the independent members of our Board of Directors determined that additional remedial action should be taken in light of prior compliance, record keeping and conflict-of-interest issues surrounding the potentially improper payment to the research lab and certain related matters. On February 26, 2013, our then-President and Chief Executive Officer and our then-General Counsel and Chief Compliance Officer resigned at the request of the independent members of our Board of Directors.

While we are continuing to cooperate with the investigations by the relevant U.S. authorities in their review of these matters and have already taken aggressive remedial steps in response to our ongoing internal investigation, these events could potentially result in lawsuits being filed against us and certain of our current or former employees and directors or we and our current or former employees and directors could be the subject of criminal or civil enforcement proceedings. In the event any such lawsuit is filed or enforcement proceeding is instigated there is no guarantee that we will be successful in defending it. Also, our insurance coverage may be insufficient and our assets may be insufficient to cover any amounts that exceed our insurance coverage, and we may have to pay penalties or damage awards or otherwise may enter into settlement arrangements in connection with such claims. A settlement of any such claims could involve the issuance of common stock or other equity, which may result in dilution to existing stockholders. Any payments or settlement arrangements could have material adverse effects on our business, operating results and financial condition. Even if any claims against us are not successful, any related litigation or enforcement proceeding, as well as the costs of investigation, could result in substantial costs and significantly and adversely impact our reputation and divert management's attention and resources, which could have a material adverse effect on our business, operating results and financial condition. In addition, any such lawsuit, investigation or proceeding could result in collateral consequences for our business including, among other things, making it more difficult to finance our operations, obtain certain types of insurance (including directors' and officers' liability

insurance), enter into collaboration agreements and attract and retain qualified executive officers, other employees and directors. If we are unable to effectively manage these risks, our business, operating results or financial condition may be adversely affected.

## We have limited experience as a company in marketing drug products and managing a sales and marketing organization.

Our strategy is to build a fully-integrated biopharmaceutical company to successfully execute the commercialization of DIFICID in the United States and Canada. Although we have engaged Cubist as our exclusive partner to co-promote DIFICID in the United States, we have limited experience commercializing pharmaceutical products on our own. In order to commercialize products, in addition to our engagement of Cubist, we have established our own marketing, sales, distribution, pharmacovigilance, managerial and other non-technical capabilities. The establishment and development of our own sales force to market DIFICID has been, and will continue to be, expensive and time consuming, and we cannot be certain that we will be able to successfully maintain this capability or successfully adapt it to commercialize any future products we may develop or acquire. Our agreement with Cubist could terminate early, and our commercial presence may not be sufficient to adequately market DIFICID in the United States on our own. In addition, if our agreement with Cubist is not renewed beyond July 2013, we may be unable to successfully replace the resources and efforts of Cubist in co-promoting DIFICID in the United States. We 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, including those of APEL in Europe and Cubist in the United States. In the event we are unable to further develop and maintain our own marketing and sales capabilities or collaborate with a third-party marketing and sales organization, we would not be able to fully commercialize any product, including DIFICID, which would negatively impact our ability to generate product revenues.

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

We have outsourced all manufacturing of supplies of our products and product candidates to third parties. We seek to establish long-term supply arrangements with third-party contract manufacturers. For example, in May 2010, we entered into a long-term supply agreement with Biocon for the commercial manufacturing of the API for fidaxomicin, and in June 2011, we entered into a manufacturing services agreement with Patheon to manufacture and supply certain fidaxomicin products, including DIFICID. Biocon currently is our sole source of supply for fidaxomicin API and Patheon currently is our sole source of supply for finished fidaxomicin drug product. We intend to continue outsourcing the manufacture of our products and 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, such as DIFICID.

Our ability and that of our collaborators to develop and commercialize fidaxomicin and any other product candidates will depend, in part, on our ability and that of our collaborators to arrange for third parties to manufacture our products at a competitive cost, in accordance with strictly enforced regulatory requirements and in sufficient quantities for regulatory approval, commercialization and any future clinical trials. 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. Further, development of large-scale manufacturing processes will require additional validation studies, which the FDA must review and approve. Difficulties in establishing these required manufacturing processes could result in delays in clinical trials, regulatory submissions and approvals, or commercialization of our product candidates.

While we work closely with Biocon and Patheon to try to ensure continuity of supply while maintaining high quality and reliability, we cannot guarantee that these efforts will be successful, and we do not have secondary sources of supply to replace these third parties. 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 involve a substantial amount of time and cost and such supply arrangements may not be available on acceptable economic terms. A reduction or interruption in our supply of fidaxomicin API or drug product from our current suppliers, and an inability to develop alternative sources for such supply, could adversely affect our ability to obtain fidaxomicin in a timely or cost effective manner to maximize product sales, and could result in a breach of our supply agreements with APEL, Astellas Japan, other collaboration partners or our co-promotion agreement with Cubist, which could result in any of those parties terminating their respective agreements with us.

In addition, our collaborators, we and other third-party manufacturers of our products must comply with strictly enforced current good manufacturing practices, or 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 currently rely on Biocon to manufacture fidaxomicin API and rely on Patheon to manufacture the finished drug product. 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. The manufacturing facilities of Biocon and Patheon have been inspected and approved by the FDA for other companies' drug products; however, none of Biocon's or Patheon's facilities has been inspected by the FDA for the manufacture of our drug supplies. Third-party manufacturers of our products and we may be unable to comply with cGMP requirements and with other FDA, state, local and foreign regulatory requirements. Our collaborators and we 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 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, our collaborators and we may not be able to obtain or maintain regulatory approval for or successfully commercialize one or more of our products, which would significantly harm our business and prospects.

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

Our products and product candidates compete or will compete against both branded and generic antibiotic therapies. With respect to DIFICID, we face competition from branded Vancocin Pulvules, generic vancomycin capsules, reconstituted intravenious vancomycin "slurry" for oral administration and metronidazole. In addition, we anticipate that DIFICID will compete with other antibiotic and anti-infective product candidates currently in development for the treatment of CDAD. For example, Cubist has initiated a Phase 3 clinical trial for its compound, CB-183,315, as a potential treatment for CDAD. Many of these products have been or will be developed and marketed by major pharmaceutical companies, who have significantly greater financial resources and expertise than we do in research and development, preclinical testing, conducting clinical trials, obtaining regulatory approvals, manufacturing and marketing approved products. 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 also may prove to be significant competitors, particularly through collaborative arrangements with large, established pharmaceutical or other companies.

DIFICID currently faces, and we anticipate it will continue to face, increasing competition in the form of generic versions of branded products. For example, DIFICID currently faces direct competition from an inexpensive generic form of metronidazole and vancomycin capsules in the United States. In Europe, DIFICLIR faces generic oral vancomycin competition. In addition, our internal market research suggests that there is continued significant use of oral reconstituted intravenous vancomycin "slurry" in the hospital setting. Generic antibiotic therapies typically are sold at lower prices than branded antibiotics and generally are preferred by managed care providers of health services. For example, because metronidazole and generic vancomycin "slurry" are available at such a low price and because generic vancomycin capsules are available at a low price, we believe it may be difficult to sell DIFICID as a firstline therapy for the treatment of CDAD. Even if physicians prescribe DIFICID to their patients, the relatively high cost of DIFICID compared to generic alternatives may cause patients not to fill their retail prescriptions or cause pharmacists to try to convert DIFICID prescriptions to generic alternatives. If our collaborators or 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 DIFICID 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 lower recurrence rates, have fewer side effects or are less expensive than our product candidates.

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.

An important part of our business strategy is to continue to develop a pipeline of product candidates by developing new indications for fidaxomicin or 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 or licenses;

- higher than expected acquisition and integration costs;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers, customers or partners 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.

## 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 inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials 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 preclinical studies and initial clinical testing. In addition, sub-analysis of clinical trial data may reveal limitations even though top-line results are positive. The type and amount of clinical data necessary to gain regulatory approval also may change during or after completion of clinical trials or we may inaccurately characterize such requirements. Moreover, we cannot guarantee that the FDA or comparable foreign regulatory authorities will agree with our interpretation of clinical trial data, or find such data sufficient to grant product approval. There are also risks that post-approval clinical trials we are conducting, agreed to conduct or otherwise plan to conduct with respect to DIFICID will not yield positive results, which would impair our ability to continue marketing DIFICID in the United States.

## 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 have, in the past, experienced delays in clinical trials of our product candidates, and we may experience delays in ongoing or future clinical trials. We do not know whether our 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.

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. If we experience delays in the completion of, or termination of, any clinical trial, the commercial prospects of our product candidates may 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 or negatively affect sales of any marketed product.

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 our Phase 3 clinical trials of DIFICID, the most common drug-related side effects reported were nausea, vomiting, constipation, anorexia, headache and dizziness. If adverse, drug-related events are encountered or suspected, 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. Adverse events encountered in any post-approval studies also may harm our efforts and those of our collaborators to market our product candidates or could result in withdrawal of regulatory approvals. 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 have relied on, and currently 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, our collaborators and we may not be able to obtain or maintain regulatory approval for or commercialize our product candidates.

We have entered into agreements with third-party CROs to provide monitors for and to manage data for our clinical programs, including our Phase 3b clinical trial of DIFICID for the prevention of CDAD in patients undergoing HSCT.

We, and any CROs conducting clinical trials for us, 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 that conduct 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 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 or could prevent us from complying with post-approval study requirements.

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 clinical programs. These CROs may have relationships with other commercial entities, including our competitors, for whom they may 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 are 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 or may have to be repeated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates or our ability to comply with post-approval study requirements could be jeopardized. 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.

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

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

In March 2010, PPACA became law in the United States PPACA substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Among the provisions of PPACA of greatest importance to the pharmaceutical industry are the following:

- an annual, non-deductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their overage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals which began in April 2010 and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level beginning in 2014, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians, including reporting any "transfer of value" made or distributed to prescribers and other healthcare providers, effective March 30, 2013, and reporting any investment interests held by physicians and their immediate family members during the preceding calendar year;
- a new requirement to report annually drug samples that manufacturers and distributors provide to physicians;
- a licensure framework for follow-on biologic products; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research.

We anticipate that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and an additional downward pressure on the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

We cannot be certain that DIFICID or any future approved products will successfully be placed on the list of drugs covered by particular health plan formularies, nor can we predict the negotiated price for any future products, which will be determined by market factors. Many states have created preferred drug lists and include drugs on those lists only when the manufacturers agree to pay a supplemental rebate. If DIFICID or any future products 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 the PPACA and the trend toward cost-effectiveness criteria and managed healthcare in the United States, third-party payors increasingly are attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new drugs. They also may 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 coverage and 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 DIFICID. We 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.

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 products and product candidates and other hazardous compounds.

Our manufacturers and we 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 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 commercialization activities or drug development programs. 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, the commercialization of our products may be harmed 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 products and 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 and 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 and product candidates but that are not covered by the claims of our pending patent applications or owned 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 and product candidates or components of our product formulations that are not covered by the claims of our owned or licensed patents, not licensed to us under our license agreements or are subject to patents that expire;
- our licensors and we might not have been the first to make the inventions covered by our patents and patent applications or the pending patent applications and issued patents of our licensors;
- our licensors or we 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 we own or license 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 our products and 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 for any product.

We have 16 pending patent applications and 5 issued patents related to fidaxomic from the United States Patent and Trademark Office, or U.S.P.T.O. These patents and patent applications related to fidaxomic encompass various topics relating to:

- composition of matter for fidaxomicin;
- pharmaceutical composition of fidaxomicin and use for CDI;
- polymorphic forms (issued in the United States);
- composition comprising a polymorphic form (issued in the United States);
- manufacturing processes (issued in the United States);
- treatment of diseases with fidaxomicin (issued in the United States);
- formulation; and
- fidaxomicin-related compounds, including metabolites (issued in the United States).

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 fidaxomicin. Furthermore, our competitors, including generic drug companies, may be able to design around our existing patents and pending applications which may issue as patents for fidaxomicin. As a result, our competitors may be able to develop competing products.

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. We may be dependent on Par to provide technical support for patent applications relating to fidaxomicin. If Par fails to adequately protect fidaxomicin with issued patents, our business and prospects would be significantly harmed.

We 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 knowhow.

If our licensees or we 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 or, as applicable, our commercialization partners pursuant to their first right to enforce the patents licensed to them in their respective territories, 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 or our commercialization partners 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 commercialization 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 DIFICID, these searches may not have identified all third-party patents relevant to this product and we have not conducted an extensive search of patents issued to third parties with respect to our 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.

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 U.S. 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 continue to 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:

- general economic and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors;
- actual or anticipated variations in our quarterly operating results, including fidaxomicin sales and royalties, and our quarterly expenses;

- announcement of foreign regulatory agency approval or non-approval of our or our competitors' product candidates, or specific label indications for their use, or delays in the foreign regulatory agency review process;
- actions taken by the FDA or other regulatory agencies with respect to our product or product candidates; clinical trials, manufacturing process or marketing and sales activities;
- failure of fidaxomicin to achieve commercial success;
- 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 DIFICID;
- announcements by our collaborators with respect to clinical trial results, regulatory submissions 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 development and commercialization partners;
- our dependence on our collaborators, such as APEL, Astellas Japan, STA and AstraZeneca, to commercialize and further develop our products in foreign countries in compliance with foreign regulatory schemes;
- our failure to successfully execute our commercialization strategy with respect to our products following marketing approval thereof:
- the success of our continuing efforts to establish and build marketing and sales capabilities;
- inability to obtain adequate commercial supply for any product following marketing approval thereof, or inability to do so at acceptable prices;
- 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;
- the development of generic product alternatives to our or our competitors' products;
- third-party coverage or reimbursement policies;
- changes in government regulations affecting product approvals, reimbursement or other aspects of our or our competitors' business;
- 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;
- 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.

We have registered all common stock that we have issued 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, certain of our directors and executive officers have established, and others may in the future establish, programmed selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended, or the 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.

## We have identified a material weakness in our internal control over financial reporting which could, if not remediated, result in material misstatements in our financial statements.

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. As disclosed in Item 9A, management identified a material weakness in our internal control over financial reporting related to approval of certain non-recurring transactions. A material weakness is defined as a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. As a result of this material weakness, our management concluded that our internal control over financial reporting was not effective based on criteria set forth in the "Internal Control-Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission. We believe that the steps that we have taken over the past year have remediated the issues that contributed to the material weakness. These steps included the revision of our corporate authorization policy and other compliance policies, the strengthening of our approval procedures, the implementation of training and internal audit procedures to make our compliance and monitoring more comprehensive and changes to our senior management team, concluding with the replacement of our Chief Executive Officer and General Counsel in February 2013. If our remedial measures are insufficient to address the material weakness, or if additional material weaknesses or significant deficiencies in our internal control are discovered or occur in the future, our consolidated financial statements may contain material misstatements and we could be required to restate our financial results.

# 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;
- 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.

## We adopted a rights plan that could make it more difficult for a third-party to acquire us.

On February 26, 2013, our Board of Directors adopted a stockholder rights plan in conjunction with deciding to conduct a review of strategic alternatives. The plan could discourage, delay or prevent a third-party from acquiring a large portion of our securities, initiating a tender offer or proxy contest or acquiring us, even if our stockholders might receive a premium for their shares over then-current market prices.

## The results and impact of our announcement that we are exploring strategic alternatives cannot be determined.

On February 27, 2013, our Board of Directors announced that it has commenced a process to explore a full range of strategic alternatives. There can be no assurance that this process will result in the pursuit or consummation of any strategic transaction or that there will be a formal cessation of the process. In addition, this process may distract the attention of our Board of Directors and management from our business, cause us to incur significant expenses pursuing one or more transactions unsuccessfully or impair our relationships with customers, suppliers and employees. If we are unable to effectively manage these risks, our business, financial condition or results of operations may be adversely affected. In addition, the market price of our stock may be volatile as we consider strategic alternatives, and volatility may persist or be increased if and when a decision to pursue a particular alternative (or no alternative) is announced.

#### Item 1B. Unresolved Staff Comments

None.

#### Item 2. Properties

Our facilities consist of approximately 45,000 square feet of laboratory and office space in San Diego, California, and 24,000 square feet of office space in Jersey City, New Jersey. The lease for our San Diego facility expires in August 2022, subject to two, five-year renewal options. The lease for our facility in Jersey City expires in July 2018, subject to one, five-year renewal option.

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

In March 2012, we became aware of an attempted grant in September 2011 to Dr. Michael Chang of 1.5 million technical shares of OBI. We engaged external counsel to assist us in an internal review and determined that the attempted grant may have violated certain applicable laws, including the FCPA.

In April 2012, we self-reported the results of our preliminary findings to the SEC and the DOJ, which included information about the attempted grant and certain related matters, including a potentially improper \$300,000 payment in July 2011 to a research laboratory involving an individual associated with the OBI share grant. At that time, we terminated the employment of our then-Chief Financial Officer and our then-Vice President, Clinical Development. We also removed Dr. Michael Chang as the Chairman of our Board of Directors and requested that Dr. Michael Chang resign from the Board of Directors, which he has not. We continued our investigation and our cooperation with the SEC and the DOJ.

As a result of our continuing internal investigation, in February 2013, the independent members of our Board of Directors determined that additional remedial action should be taken in light of prior compliance, record keeping and conflict-of-interest issues surrounding the potentially improper payment to the research laboratory and certain related matters. On February 26, 2013, our then-President and Chief Executive Officer and our then-General Counsel and Chief Compliance Officer resigned at the request of the independent members of our Board of Directors.

In addition, over the past year, we have revised our compliance policies, strengthened our approval procedures and implemented training and internal audit procedures to make our compliance and monitoring more comprehensive.

We continue to cooperate with the SEC and DOJ, including by responding to informal document and interview requests, conducting in-person meetings and updating these authorities on our findings with respect to the attempted OBI technical share grant, the potentially improper payment to the research laboratory and certain matters that may be related. We are unable to predict the ultimate resolution of these matters, whether we will be charged with violations of applicable civil or criminal laws or whether the scope of the investigations will be extended to new issues. We also are unable to predict what potential penalties or other remedies, if any, the authorities may seek against us or any of our current or former employees, or what the collateral consequences may be of any such government actions.

#### Item 4. Mine Safety Disclosures.

Not applicable.

#### **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 Stock Market under the symbol "OPTR" since February 9, 2007. Prior to that time, there was no public market for our common stock. The following table sets forth the range of high and low sale prices for our common stock reported by Nasdaq Global Select Market.

2012	High			Low	
First Quarter	\$	14.23	\$	11.68	
Second Quarter	\$	16.00	\$	11.87	
Third Quarter	\$	16.39	\$	12.86	
Fourth Quarter	\$	14.17	\$	8.64	
2011		High		Low	
First Quarter	\$	13.00	\$	10.50	
Second Quarter	\$	14.74	\$	11.75	
Third Quarter	\$	17.95	\$	6.81	
Fourth Quarter	\$	15.40	\$	10.00	

As of February 15, 2013, there were approximately 24 holders of record of our common stock.

#### **Dividends**

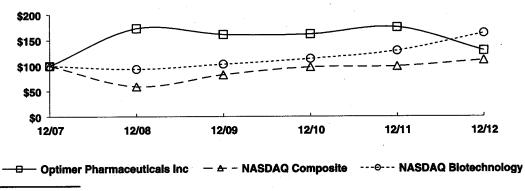
We have never paid or declared cash dividends on our capital stock. We currently intend to retain future earnings, if any, for use in the expansion and operation of our business.

#### **Performance Measurement Comparison**

The following stock performance graph illustrates a comparison of the annual percentage change in the cumulative total stockholder return on our common stock. The graph assumes an investment of \$100 on December 31, 2007, and that all dividends were reinvested.

## COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\*

Among Optimer Pharmaceuticals Inc, the NASDAQ Composite Index, and the NASDAQ Biotechnology Index



<sup>\*\$100</sup> invested on 12/31/07 in stock or index, including reinvestment of dividends.

#### 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,							
		2012	2011 2010		2009			2008		
				(in thousar	ıds, e	xcept per share	amo	ounts)		
Statement of Operations Data:		60.417	٨		Φ.		Φ.			
Product revenue, net	\$	62,417	\$	21,511	\$		\$		\$	-
Contract revenue		39,112		122,749						
Other		2		718		1,480		893		1,023
Total revenues		101,531		144,978		1,480		893		1,023
Operating expenses:										
Cost of product sales		5,486		1,526		<del></del>		_		
Cost of contract revenue		6,463		7,584				_		
Research and development		45,202		43,085		32,797		34,417		30,206
Selling, general and administrative		112,026		80,574		17,551		9,074		7,964
Co-promotion expenses with Cubist		23,191		6,570						
Total operating expenses		192,368		139,339		50,348		43,491		38,170
Income (loss) from operations		(90,837)		5,639		(48,868)	_	(42,598)		(37,147)
Gain on de-consolidation of OBI		23,782		_				_		<del>-</del>
Gain on sale of OBI shares		31,501								
Equity in net loss of OBI		(1,849)								
Interest income and other, net		136		291		329		364		1,562
Consolidated net income (loss)		(37,267)		5,930		(48,539)	_	(42,234)		(35,585)
Net loss attributable to non-controlling		(= . ,= )		-,		(10,000)		( -, 1)		(00,000)
interest		280		1,892		1,199		142		
Net income (loss) attributable to Optimer									-	
Pharmaceuticals, Inc.	\$	(36,987)	\$	7,822	\$	(47,340)	\$	(42,092)	\$	(35,585)
Net income (loss) per share attributable to	<u> </u>	(= 1,1 = 1)	÷	.,,	<u> </u>		Ť	( , , , , , , , , , , , , , , , , , , ,		(,)
common stockholders - basic	\$	(0.78)	\$	0.17	\$	(1.25)	\$	(1.30)	\$	(1.24)
	Ψ	(0.76)	Ψ	0.17	Ψ	(1.23)	Ψ	(1.50)	Ψ	(1.24)
Net income (loss) per share attributable to common stockholders - diluted	ø	(0.79)	ď	0.17	ø	(1.25)	ø	(1.20)	ø	(1.24)
	<b>D</b>	(0.78)	<u>\$</u>	0.17	<u>\$</u>	(1.25)	<u>\$</u>	(1.30)	<u>\$</u>	(1.24)
Weighted average shares outstanding - basic	_	47,332	_	45,622	_	37,830		32,469	1	28,683
Weighted average shares outstanding -										
diluted		47,332		46,369		37,830		32,469		28,683
					De	ecember 31,				
,		2012		2011		2010		2009		2008
Th. 1. (1. 4.Th.)					(in	thousands)				
Balance Sheet Data:										
Cash, cash equivalents and short-term	ф	124.001	Φ	110.570	Φ	40.41.5	Φ	20.105	ф	20.226
investments	\$		\$	110,579	\$	49,415	\$	38,185	\$	39,326
Working capital		125,228		145,853		45,239		30,951		32,258
Total assets		159,427		182,023		52,020		40,656		42,295
Accumulated deficit		(251,979)		(214,993)		(222,814)		(175,475)		(133,382)
Non-controlling interest				6,661		1,997		3,040		<del></del>
Total stockholders' equity		130,810		150,564		47,186		32,752		34,231

## 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 global biopharmaceutical company currently focused on commercializing our antibiotic product DIFICID® (fidaxomicin) in the United States and Canada, and on developing other fidaxomicin products in the United States and worldwide, both independently and with our partners and licensees. DIFICID is a macrolide antibacterial drug indicated in adults 18 years of age or older for the treatment of CDAD and is the first antibacterial drug to be approved in the United States for the treatment of CDAD in more than 25 years. We currently are marketing DIFICID in the United States through our own sales force and through our copromotion agreement with Cubist Pharmaceuticals, Inc., or Cubist.

We continue to pursue regulatory approval for, and commercialization of, fidaxomicin in other geographies outside the United States and Canada through various collaboration partners. In December 2011, the European Medicines Agency, or EMA, approved the Marketing Authorization Application, or MAA, for DIFICLIR (fidaxomicin) for the treatment of adults suffering from CDI in Europe. In June 2012, our collaboration partner, Astellas Pharma Europe Ltd., or APEL, achieved the first sales of DIFICLIR tablets in its European territories. In addition, in June 2012, our subsidiary Optimer Pharmaceuticals Canada, Inc., or Optimer Canada, began marketing DIFICID in Canada. We have entered into agreements with Astellas Pharma Inc., or Astellas Japan, and with Specialised Therapeutics Australia Pty. Ltd, or STA, for the development and commercialization of fidaxomicin in Japan and in Australia and New Zealand, respectively. In November 2012 we entered an exclusive agreement with AstraZeneca UK Limited, or AstraZeneca, to commercialize fidaxomicin tablets for the treatment of CDI in Latin America, including Brazil, Central America, Mexico and the Caribbean.

We were incorporated in November 1998 and have incurred significant net losses since our inception. At December 31, 2012, we had an accumulated deficit of \$252.0 million. These losses have resulted principally from costs incurred in connection with research and development activities, including the costs of clinical trial activities, license fees and general and administrative expenses and, more recently, expenses incurred in connection with our commercial efforts with respect to DIFICID in the United States and Canada. We expect to incur operating losses for at least the next two years as we commercialize DIFICID and pursue further development of DIFICID, including conducting post-marketing studies for label expansion and continuing further development, regulatory approval and commercialization of fidaxomicin worldwide. For example, in October 2012, we initiated a Phase 3b clinical trial of DIFICID for the prevention of CDAD in patients undergoing HSCT. We may acquire or in-license additional products or product candidates, technologies or businesses that are complementary.

#### **Recent Developments**

On February 26, 2013, the Board of Directors appointed Henry A. McKinnell, Ph.D., the Chairman of our Board of Directors, as our Chief Executive Officer. Dr. McKinnell replaced Pedro Lichtinger, who served as our President and Chief Executive Officer beginning in May 2010. The Board of Directors also appointed Meredith Schaum to replace Kurt Hartman as our General Counsel and Chief Compliance Officer. The independent members of the Board of Directors recommended to the Board of Directors that the foregoing management changes were appropriate following their review of prior compliance, record keeping and conflict-of-interest issues observed during the review, including issues arising from the conduct of our personnel who were the subject of the changes in management and leadership announced in April 2012. The previously disclosed investigations of these issues by the relevant U.S. authorities are ongoing and we are continuing to cooperate with those authorities (see "Legal Proceedings").

In connection with Mr. Lichtinger's resignation, we expect to enter into a separation agreement, pursuant to which he will receive the following benefits: (i) an amount equal to 24 months of his base salary and a cash bonus based on 2012 performance, in each case less applicable tax withholdings; (ii) 24 months of continued group health benefits; and (iii) acceleration of 30,500 unvested restricted stock units and 230,292 unvested stock options with a weighted average exercise price of \$12.53.

In connection with Mr. Hartman's resignation, we entered into a separation agreement with Mr. Hartman, executed on March 2, 2013, pursuant to which he will receive the following benefits: (i) an amount equal to 15 months of his base salary and a cash bonus based on 2012 performance, in each case, less applicable tax withholdings; (ii) 15 months of continued group health benefits; and (iii) acceleration of 1,167 unvested restricted stock units and 37,109 unvested stock options with a weighted average exercise price of \$10.18.

On February 27, 2013, our Board of Directors announced that it had commenced a process to explore a full range of strategic alternatives, including a possible sale of the Company. In connection with this process, we have engaged J.P. Morgan and Centerview Partners as our financial advisers. There can be no assurance that this process will result in the pursuit or consummation of any strategic transaction or that there will be a formal cessation of the process. In addition, we may incur significant expenses pursuing one or more transactions unsuccessfully (see "Risk Factors — The results and impact of our announcement that we are exploring strategic alternatives cannot be determined."). In conjunction with this process, our Board of Directors adopted a stockholder rights plan to protect our stockholders while the strategic review is being conducted.

#### **Financial Operations Overview**

#### Revenues

DIFICID is available in the United States and Canada through three major wholesalers - AmerisourceBergen Corporation, Cardinal Health, Inc. and McKesson Corporation - and through regional wholesalers and specialty pharmacies that provide DIFICID to purchasing customers, such as hospitals, retail pharmacies, long-term care facilities and other purchasing outlets that may dispense DIFICID. We recognize revenue from product sales when persuasive evidence of an arrangement exists, delivery has occurred, title has passed to the customer, the price is fixed and determinable, the buyer is obligated to pay us, the obligation to pay is not contingent on resale of the product, the buyer has economic substance apart from us, we have no obligation to bring about the sale of the product, the amount of returns can be reasonably estimated and collectability is reasonably assured. We recognize product sales of DIFICID upon delivery of product to the wholesalers, specialty pharmacies and certain direct purchasers.

Contract revenue is generated from collaboration partners and includes up-front and milestone payments, product sales and royalties.

Prior to the launch of DIFICID, we generated revenues primarily as a result of various collaborations with pharmaceutical and biotechnology companies and grants from government agencies. Revenues from license and collaboration agreements are recognized based on the performance requirements of the underlying agreements. Revenue is deferred for fees received before they are earned. Non-refundable, up-front payments and license fees, where we have an ongoing involvement or performance obligation, are recorded as deferred revenue and recognized as revenue over the contract or development period. Milestone payments generally are recognized as revenue upon the achievement of the milestones as specified in the underlying agreement, assuming we meet certain criteria. Royalty revenues from the sale of fidaxomicin are recognized upon the sale of product.

#### Cost and Expenses

Cost of Product Sales. Cost of product sales consists of the costs to manufacture and ship DIFICID in support of U.S. and Canadian sales, as well as royalties due on such sales.

Cost of Contract Revenue. Cost of contract revenue consists of the cost of pharmaceutical product sales to our collaborators, as well as royalties due on contract revenue recognized.

Research and Development Expense. Research and development expense consists of expenses incurred in connection with developing our drug candidates. Our research and development expenses consist primarily of salaries and related employee benefits and costs associated with clinical trials. Research and development expense also includes the costs associated with our medical affairs and health outcomes and economic research efforts. 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, 2012, we incurred total research and development expenses of approximately \$268.2 million.

Selling, General and Administrative Expense. Selling, general and administrative expense consists primarily of compensation, including stock-based compensation, related to our commercial operations and administrative employees and other expenses related to an allocated portion of facility costs, legal fees and other professional services expenses and insurance costs.

Co-promotion Expenses with Cubist. Co-promotion expenses with Cubist consist of co-promotion fees and any bonus and profit-share earned by Cubist.

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. At December 31, 2012, we had federal, state and foreign net operating loss carryforwards of approximately \$184.0 million, \$195.1 million, and \$7.3 million, respectively. If not utilized, the net operating loss carryforwards will begin expiring in 2020 for federal purposes and in 2015 for state purposes. The foreign net loss carryforwards

will begin expiring in 2019. At December 31, 2012, we had both federal and state research and development tax credit carryforwards of approximately \$7.0 million and \$4.7 million, respectively. The federal tax credits will begin expiring in 2020 unless previously utilized and the state tax credits carry forward indefinitely. At December 31, 2012, we had a state manufacturer's investment tax credit carryforward of approximately \$47,000 that began expiring in 2012. 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 to offset taxable income. Any such annual limitation may significantly reduce the utilization of the net operating losses and tax credits before they expire.

In 2012, we completed a Section 382/383 analysis regarding the limitation of the net operating losses and credit carryovers and determined that the entire amount of U.S. federal and state net operating losses and credit carryovers are available for utilization, subject to an annual limitation. Any carryforwards that will expire, prior to utilization and as a result of future limitation, will be removed from deferred tax assets with a corresponding reduction of the valuation allowance. Due to the existence of the valuation allowance, future changes in the unrecognized tax benefits will not impact the effective tax rate.

The American Taxpayer Relief Act of 2012, which reinstated the U.S. Federal Research and Development Tax Credit retroactively from January 1, 2012 through December 31, 2013, was not enacted into law until the first quarter of 2013. Therefore, the expected tax benefit resulting from such reinstatement for 2012 will not be reflected in the Company's estimated annual effective tax rate until 2013.

#### **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.

#### **Product Sales**

During the year ended December 31, 2012, the \$62.4 million in net product sales to wholesalers reflected a total of 26,628 DIFICID treatments shipped to wholesalers and specialty pharmacies. Wholesalers and specialty pharmacies shipped approximately 25,700 DIFICID treatments to hospitals, retail pharmacies, long-term care facilities and other purchasing outlets that may dispense DIFICID in the United States and Canada. Our sales representatives primarily target approximately 1,200 hospitals, although approximately 2,800 hospitals have ordered DIFICID.

Our net product sales represent total gross product sales in the United States and Canada less allowances for customer credits, including estimated rebates, chargebacks, discounts and returns. These allowances are established by management as its best estimate, based on available information, and are adjusted to reflect known changes in the factors that impact such allowances. Allowances for rebates, chargebacks, discounts and returns are established based on the contractual terms with customers, communications with customers, as well as expectations about the market for the product and anticipated introduction of competitive products. Product shipping and handling costs are included in cost of sales.

Product Sales Allowances. We establish reserves for prompt-payment discounts, fee-for-service arrangements, government and commercial rebates, product returns and other applicable allowances, such as our hospital discount. Allowances relate to prompt-payment discounts and fee-for-service arrangement with our contracted wholesalers and direct purchase discounts, and are recorded at the time of sale, resulting in a reduction in product sales revenue. Accruals related to government and commercial rebates, product returns and other applicable allowances are recognized at the time of sale, resulting in a reduction in product sales and an increase in accrued expenses.

Prompt-payment Discounts. We offer a prompt-payment discount to our customers. Since we expect our customers will take advantage of this discount, we accrue 100% of the prompt-payment discount that is based on the gross amount of each invoice, at the time of sale. The accrual is adjusted quarterly to reflect actual earned discounts.

Government and Commercial Rebates and Chargebacks. We estimate commercial rebates as well as government-mandated rebates and discounts relating to federal and state programs such as Medicaid, the Veterans' Administration, or VA, and Department of Defense programs, the Medicare Part D Coverage Discount Program and certain other qualifying federal and state government programs. We estimate the amount of these rebates and chargebacks based on historical trends for DIFICID. These allowances are adjusted each period based on actual experience.

Medicaid rebate reserves relate to our estimated obligations to states under statutory "best price" obligations which also may include supplemental rebate agreements with certain states. Rebate accruals are recorded during the same period in which the related product sales are recognized. Actual rebate amounts are determined at the time of claim by the state, and we generally will make cash payments for such amounts after receiving billings from the state.

VA rebates or chargeback reserves represent our estimated obligations resulting from contractual commitments to sell DIFICID to qualified healthcare providers at a price lower than the list price charged to our distributors. A distributor will charge us for the difference between what the distributor pays for the product and the ultimate selling price to the qualified healthcare provider. Rebate and chargeback accruals are established during the same period in which the related product sales are recognized. Actual chargeback amounts for Public Health Service are determined at the time of resale to the qualified healthcare provider from the distributor, and we generally will issue credits for such amounts after receiving notification from the distributor.

Although allowances and accruals are recorded at the time of product sale, certain rebates generally will be paid, on average, in six months or longer after the sale. Reserve estimates are evaluated quarterly and, if necessary, adjusted to reflect actual results. Any such adjustments will be reflected in our operating results in the period of the adjustment. For the year ended December 31, 2012, there were no material adjustments.

Product Returns. Our policy in the United States is to accept returns of DIFICID for six months prior to, and twelve months after, the product expiration date. Our policy in Canada is to accept returns of DIFICID for three months prior to, and twelve months after, the product expiration date. We permit returns if the product is damaged or defective when received by our customers. We will provide a credit for such returns to customers with whom we have a direct relationship. Once product is dispensed it cannot be returned, but we allow partial returns in states where such returns are mandated. We do not exchange product from inventory for the returned product.

Allowances for product returns are recorded during the period in which the related product sales are recognized, resulting in a reduction to product revenue. We estimate product returns based upon the sales pattern of DIFICID, management's experience with similar products, historical trends in the pharmaceutical industry and trends for similar products sold by others.

During the years ended December 31, 2012 and 2011, the provisions for product sales allowances reduced gross product sales as follows:

		2012		2011
Total gross product sales	\$	74,890,803	\$	24,357,200
Returns reserve and allowance	\$ \$	(1,583,723) (4,947,295) (5,942,630) (12,473,648) 62,417,155	<u>\$</u>	(365,358) (476,116) (2,004,689) (2,846,163) 21,511,037
Total product sales allowances as a percent of gross product sales		16.7%	, 6 =	11.7%

An analysis of the amount of, and change in, reserves for the years ended December 31, 2012 and 2011 is as follows:

	Returns Reserve and Allowances	Government and Commercial Rebates and Chargebacks	Prompt-pay Discounts and Fees	Total
Balance at January 1, 2011	\$ <del>-</del>	\$ —	\$ —	\$ —
Provisions related to sales in the current				
year	365,358	476,116	2,004,689	2,846,163
Returns and payments		(106,218)	(429,403)	(535,621)
Balance at December 31, 2011	365,358	369,898	1,575,286	2,310,542
Provisions related to sales in the current				
year	1,583,723	4,988,805	5,953,674	12,526,202
Provisions related to sales made in prior	, ,	• •		
year	-	(41,510)	(11,044)	(52,554)
Returns and payments	(473,957)	(3,674,344)	(5,629,393)	(9,777,694)
Balance at December 31, 2012	\$ 1,475,124	\$ 1,642,849	\$ 1,888,523	\$ 5,006,496

#### Contract Revenue

Under certain of our licensing and collaboration agreements, we are entitled to receive payments upon the achievement of contingent milestone events. In order to determine the revenue recognition for contingent milestone-based payments, we evaluate the contingent milestones using the criteria as provided by the Financial Accounting Standards Boards, or FASB, guidance on the milestone method of revenue recognition at the inception of a collaboration agreement.

Accounting Standard Codification (ASC) Topic 605-28, Revenue Recognition — Milestone Method (ASC 605-28), established the milestone method as an acceptable method of revenue recognition for certain contingent, event-based payments under research and development arrangements. Under the milestone method, a payment that is contingent upon the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is an event (i) that can be achieved based in whole or in part on either our performance or on the occurrence of a specific outcome resulting from our performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due to us. The determination that a milestone is substantive is judgmental and is made at the inception of the arrangement. Milestones are considered substantive when the consideration earned from the achievement of the milestone is (i) commensurate with either our performance to achieve the milestone or the enhancement of value of the item delivered as a result of a specific outcome resulting from our performance to achieve the milestone, (ii) relates solely to past performance and (iii) is reasonable relative to all deliverables and payment terms in the arrangement.

Other contingent, event-based payments received for which payment is either contingent solely upon the passage of time or the results of a collaborative partner's performance are not considered milestones under ASC 605-28. In accordance with ASC Topic 605-25, Revenue Recognition — Multiple-Element Arrangements (ASC 605-25), such payments will be recognized as revenue when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the price is fixed or determinable; and collectability is reasonably assured.

Revenues recognized for royalty payments are recognized as earned in accordance with the terms of various research and collaboration agreements.

For collaboration agreements with multiple deliverables, we recognize collaboration revenues and expenses by analyzing each element of the agreement to determine if it is to be accounted for as a separate element or single unit of accounting. If an element is to be treated separately for revenue recognition purposes, the revenue recognition principles most appropriate for that element are applied to determine when revenue is to be recognized. If an element is not to be treated separately for revenue recognition purposes, the revenue recognition principles most appropriate for the bundled group of elements are applied to determine when revenue is to be recognized.

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. In connection with certain research collaboration agreements, revenues are recognized from non-refundable up-front fees, that we do 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.

With respect to revenues derived from reimbursement of direct out-of-pocket expenses for research costs associated with grants, 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 we have received from collaborators to date, whether recognized as revenue or deferred, is refundable even if the related program is not successful.

#### Inventory

Inventory is stated at the lower of cost or market. Cost is determined using the first-in, first-out (FIFO) method. We reserve for potentially excess, dated or obsolete inventory based on an analysis of inventory on hand compared to forecasts of future sales. At December 31, 2012, inventory consisted of \$9.1 million in raw materials, \$3.6 million in work-in-process and \$2.9 million in finished goods.

#### Research and Development

We expense costs related to research and development as incurred. Our research and development expenses consist primarily of license fees, salaries and related employee benefits, costs associated with clinical trials managed by contract research organizations and costs associated with non-clinical activities and regulatory approvals. We use 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 non-refundable payments for goods or services to be received in the future for use in research and development activities are made, we defer and capitalize these types of payments. The capitalized amounts are expensed when the related goods are delivered or the services are performed.

#### Stock-based Compensation

The FASB authoritative guidance 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. Total consolidated stock-based compensation expense of \$13.0 million, \$11.8 million and \$6.4 million was recognized in the years ended December 31, 2012, 2011 and 2010, respectively. The stock-based compensation expense recognized included expense from performance-based stock options and restricted stock units.

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.

For performance-based stock options and performance-based restricted stock units, we begin to recognize the expense when it is deemed probable that the performance-based goal will be met. We evaluate the probability of achieving performance-based goals on a quarterly basis.

Equity instruments issued to non-employees are periodically revalued as the equity instruments vest and are recognized as expense over the related service period.

#### Income Taxes

We estimate income taxes based on the jurisdictions where we conduct business. Significant judgment is required in determining our worldwide income tax provision. We estimate our current tax liability and assess temporary differences that result from differing treatments of certain items for tax and accounting purposes. These differences result in net deferred tax assets and liabilities. We then assess the likelihood that deferred tax assets will be realized. A valuation allowance is recorded when it is more likely than not that some of the deferred tax assets will not be realized. We review the need for a valuation allowance each interim period to reflect uncertainties about whether we will be able to utilize deferred tax assets before they expire. The valuation allowance analysis is based on estimates of taxable income for the jurisdictions in which we operate and the periods over which our deferred tax assets may be realized. Changes in our valuation allowance could result in material increases or decreases in our income tax expense in the period such changes occur, which could have a material impact on our operating results.

At December 31, 2012, we recorded a non-current liability for uncertain income tax positions of \$0.9 million. As the liability for uncertain tax positions provides a source to support the realization of deferred tax assets, we released \$0.9 million of valuation allowance on deferred tax assets and recorded a non-current deferred tax asset of \$0.9 million at December 31, 2012.

In 2012, we recorded a tax benefit of \$281,000, which reflected our application of the intraperiod tax allocation rules under which we are required to record a tax benefit in continuing operations to offset the tax provision we recorded directly to other comprehensive income primarily related to the unrealized gain on our investment in Cempra stock.

For 2012, we estimate that we will have federal and state taxable losses. As such, no current tax provision has been recorded. We have recorded a full valuation allowance for the remaining net deferred tax benefits. In 2012, we completed a Section 382/383 analysis regarding the limitation of the net operating losses and credit carryovers and have considered the annual limitation when determining the amount available for utilization in the current year.

We recognize and measure benefits for uncertain tax positions using a two-step approach. The first step is to evaluate the tax position taken and expected to be taken in a tax return by determining if the weight of available evidence indicates that it is more likely than not that the tax position will be sustained upon audit, including resolution of any related appeals or litigation processes. For tax positions that are more likely than not to be sustained upon audit, the second step is to measure the tax benefit as the largest amount that has more than a 50% chance of being realized upon settlement. Significant judgment is required to evaluate uncertain tax positions. We evaluate uncertain tax positions on a quarterly basis. The evaluations are based upon a number of factors, including changes in facts or circumstances, changes in tax law, correspondence with tax authorities during the course of audits and effective settlement of audit issues. Changes in recognition or measurement of uncertain tax positions could result in material increases or decreases in our income tax expense in the period such changes occur, which could have a material impact on our effective tax rate and operating results.

#### Segment Reporting

Our management has determined that we operate in one business segment which is the development and commercialization of pharmaceutical products.

#### **Results of Operations**

#### Comparison of Years Ended December 31, 2012 and 2011

Product Sales, Net

Net product sales for the years ended December 31, 2012 and 2011 were \$62.4 million and \$21.5 million, respectively, an increase of \$40.9 million, or 190.2%. The increase in 2012 reflects higher demand for DIFICID, as well as a full year of sales. DIFICID was launched in July 2011.

#### Contract Revenue

Contract revenue for the years ended December 31, 2012 and 2011 was \$39.1 million and \$122.7 million, respectively, a decrease of \$83.6 million. Contract revenue is generated from collaboration partners and includes up-front and milestone payments, product sales and royalties. In 2011, contract revenue included a \$69.2 million up-front payment from APEL and a \$53.5 million milestone upon EMA approval of DIFICLIR. Contract revenue in 2012 included a \$20.0 million up-front license payment from Astellas Japan, a 10.0 million Euro milestone payment from APEL in association with the first commercial sale of DIFICLIR in an APEL territory, inventory shipments to our collaboration partners and royalty income from APEL.

#### Costs and Expenses

Cost of Product Sales. Cost of product sales for the years ended December 31, 2012 and 2011 was \$5.5 million and \$1.5 million, respectively, an increase of \$4.0 million. The increase was due to higher product sales for the year ended December 31, 2012. Additionally, a significant portion of the cost of DIFICID sold during the year ended December 31, 2011 was recorded as research and development expense when manufactured in the first quarter of 2011, as DIFICID had not been approved by the FDA at that time.

Cost of Contract Revenue. Cost of contract revenue for the years ended December 31, 2012 and 2011 was \$6.5 million and \$7.6 million, respectively, a decrease of \$1.1 million. The decrease was due to lower royalty expense associated with lower contract revenue in 2012 as compared to 2011.

Research and Development Expense. Research and development expense for the years ended December 31, 2012 and 2011 was \$45.2 million and \$43.1 million, respectively, an increase of \$2.1 million. The increase was primarily due to higher health economics and outcomes research and pharmacovigilance expenses in 2012. We also incurred expenses related to our prophylaxis and pediatric clinical trials, which began in 2012. This increase was partially offset by lower material costs associated with DIFICID production prior to FDA approval in 2011 and the combined impact of the deconsolidation of OBI and the addition of our Canadian subsidiary.

Selling, General and Administrative Expense. Selling, general and administrative expense for years ended December 31, 2012 and 2011 was \$112.0 million and \$80.6 million, respectively, an increase of \$31.4 million. The increase primarily was due to our commercialization efforts for DIFICID which included a full year of expense in 2012 and the combined impact of the deconsolidation of OBI and the addition of Optimer Canada. We also incurred higher compensation expense and higher legal and facilities expenses.

Co-promotion Expenses with Cubist. Co-promotion expenses with Cubist for the years ended December 31, 2012 and 2011 were \$23.2 million and \$6.6 million, respectively, an increase of \$16.6 million. This increase was due to a full year of co-promotion expenses, and included the year-one sales target bonus and gross profit share on sales above the target.

Gain on De-consolidation of OBI. The \$23.8 million represented the gain on the de-consolidation of OBI. We did not have a similar gain in the year ended December 31, 2011, as OBI was consolidated for that period.

Gain on Sale of OBI Shares. The \$31.5 million represented the gain on the sale of our equity investment in OBI in the fourth quarter of 2012.

Equity in Net Loss of OBI. The \$1.8 million represented the loss recognized in our investment in OBI using the equity method from February 2012 through October 2012. We did not have a similar loss in the year ended December 31, 2011, as OBI was consolidated for that period.

Interest Income and Other, Net. Net interest income and other of \$136,000 for the year ended December 31, 2012 was relatively consistent with the \$291,000 for the year ended December 31, 2011.

Net Loss Attributable to Non-controlling Interest. Net loss attributable to non-controlling interest for the years ended December 31, 2012 and 2011 was \$280,344 and \$1.9 million, respectively, a decrease of \$1.6 million. The decrease was due to the de-consolidation of OBI in 2012. The \$280,344 represented approximately one month of non-controlling interest prior to deconsolidation of OBI on February 7, 2012.

#### Comparison of Years Ended December 31, 2011 and 2010

Product Sales, Net

As DIFICID was launched in July, 2011, there were no product sales for the year ended December 31, 2010. Net product sales for the year ended December 31, 2011 were \$21.5 million.

#### Contract Revenue

As DIFICID was approved and launched in 2011, and there were no commercial collaborations established in 2010, there were no contract revenues for the year ended December 31, 2010. Contract revenue for the year ended December 31, 2011 was \$122.8 million. In 2011, contract revenue included a \$69.0 million up-front payment from APEL and a \$53.6 million milestone upon EMA approval of DIFICLIR.

#### Costs and Expenses

Cost of Product Sales. As DIFICID was launched in July 2011, there was no cost of product sales for the year ended December 31, 2010. Cost of product sales for the year ended December 31, 2011 was \$1.5 million.

Cost of Contract Revenue. As DIFICID was approved and launched in 2011, and there were no commercial collaborations established in 2010, there was no cost of contract revenue for the year ended December 31, 2010. Cost of contract revenue for the year ended December 31, 2011 was \$7.6 million, consisting primarily of royalties to Par.

Research and Development Expense. Research and development expense for the years ended December 31, 2011 and 2010 was \$43.1 million and \$32.8 million, respectively, an increase of \$10.3 million. The increase was primarily due to higher health

economics and outcomes research, medical affairs, pharmacovigilance and publication expenses, as well are higher research and development expense by OBI for its Phase 2/3 breast cancer clinical trial. The increase was partially offset by a \$5.0 million milestone payment to Par in 2010 for the successful completion of the second DIFICID Phase 3 trial.

Selling, General and Administrative Expense. Selling, general and administrative expense for the year ended December 31, 2011 and 2010 was \$87.1 million and \$17.6 million respectively, an increase of \$69.5 million. The increase primarily was due to the establishment of our commercial infrastructure for the launch of DIFICID, as well as a significant increase in related marketing expenses in 2011. We hired approximately 100 hospital account managers in mid-2011 which significantly increased our compensation expenses and related personnel costs. In addition, we expensed \$6.6 million related to the Cubist service fee as part of our co-promotion agreement.

Interest Income and Other, Net. Interest income and other, net of \$291,000 for the year ended December 31, 2011 was relatively consistent with the \$329,000 for the year ended December 31, 2010.

#### Liquidity and Capital Resources

Sources of Liquidity

Prior to the launch of DIFICID in July 2011, our operations were financed primarily through the sale of equity securities. Through December 31, 2012, we received gross proceeds of approximately \$333.8 million from the sale of equity securities in various private and public financing transactions. Since July 2011, we entered into collaboration and license agreements and received a total of approximately \$157.8 million from up-front and milestone payments pursuant to the agreements. In the fourth quarter of 2012, we sold our remaining equity interest in OBI for \$60.0 million in gross proceeds. Through December 31, 2012, we had generated \$83.9 million of net product sales.

Until required for operations, we invest a substantial portion of our available funds in marketable securities, consisting primarily of government agency securities. We have established guidelines relating to diversification and maturities of our investments to preserve principal and maintain liquidity.

#### Cash Flows

As of December 31, 2012, cash, cash equivalents and short-term investments totaled approximately \$124.0 million, as compared to \$110.6 million as of December 31, 2011, an increase of approximately \$13.4 million. The increase in our cash, cash equivalents and short-term investments was due the receipt of 50.0 million Euros from APEL in June 2012 as a result of attaining EMA approval and the commercial launch of DIFICLIR in the APEL territories. We also received a \$20.0 million up-front license payment from Astellas Japan pursuant to our collaboration and license agreement and a \$1.0 million up-front license payment from AstraZeneca. In addition, in the fourth quarter, we sold our remaining equity interest in OBI for \$60.0 million in gross proceeds.

Although we started selling DIFICID in July 2011, we cannot be certain if, when or to what extent we will receive meaningful cash inflows from our commercialization activities. We expect our commercialization expenses to be substantial. We also expect to continue to incur development expenses as we pursue life-cycle management opportunities and build our pipeline.

In December 2012, we entered into a collaboration agreement with AstraZeneca to commercialize fidaxomicin in Latin America, including Brazil, Central America, Mexico and the Caribbean. Under the terms of the agreement, we received a \$1.0 million up-front payment. We are eligible to receive up to \$3.0 million in aggregate milestone payments upon the first commercial sale in certain countries, and up to \$19.0 million in other milestone payments contingent on the achievement of sales-related targets for fidaxomicin in the territories. We also are entitled to receive payments that provide a return resulting in a double-digit percent of net sales in the territory under a fidaxomicin supply agreement.

In March 2012, we entered into a collaboration and license agreement with Astellas Japan pursuant to which we granted to Astellas Japan an exclusive, royalty-bearing license under certain of our know-how and intellectual property to develop and commercialize fidaxomicin in Japan. Under the terms of the license agreement, Astellas Japan paid to us an up-front fee equal to \$20.0 million which we received in April 2012. We also are eligible to receive additional cash payments totaling up to \$70.0 million upon the achievement by Astellas Japan of specified regulatory and commercial milestones. In addition, we are entitled to receive high single-digit royalties on net sales of fidaxomicin products in Japan above an agreed threshold, which royalties are subject to reduction in certain, limited circumstances. Such royalties will be payable by Astellas Japan on a product-by-product basis until a generic product accounts for a specified market share of the applicable fidaxomicin product in Japan. Under the supply agreement, in exchange for commercial supply of fidaxomicin, Astellas Japan is obligated to pay Optimer Europe a price equal to net sales of fidaxomicin products in Japan minus a discount that is based on a high double-digit percentage of such net sales and a mark-up to cost

of goods. This price will be payable by Astellas Japan on a product-by-product basis for commercial supply until a generic product accounts for a specified market share of the applicable fidaxomicin product in Japan.

In April 2011, we entered into a co-promotion agreement with Cubist pursuant to which we engaged Cubist as our exclusive partner for the promotion of DIFICID in the United States. Under the terms of the agreement, Cubist and we have agreed to co-promote DIFICID to physicians, hospitals, long-term care facilities and other healthcare institutions as well as jointly provide medical affairs support for DIFICID. In exchange for Cubist's co-promotion activities and personnel commitments, we are obligated to pay a quarterly fee of approximately \$3.8 million to Cubist which we began paying upon the commencement of the DIFICID sales program in the United States. Cubist also is eligible to receive an additional \$5.0 million in the first year after first commercial sale and \$12.5 million in the second year after first commercial sale if mutually agreed upon annual sales targets are achieved, as well as a portion of our gross profits derived from net sales above the specified annual targets, if any. During 2012, we achieved the first year sales target and paid Cubist \$23.2 million, which consisted of \$14.7 million in quarterly co-promotion fees, \$5.0 million for the year-one sales target bonus and \$3.5 million for Cubist's portion of the gross profit on net sales above the year-one target. We currently do not anticipate renewing the co-promotion agreement when it expires on July 31, 2013, and will evaluate expanding our field force to detail the hospitals currently covered only by a Cubist representative.

In June 2011, we entered into a commercial manufacturing services agreement with Patheon to manufacture and supply fidaxomic drug products, including DIFICID, in North America, Europe and other countries, subject to agreement by the parties to any additional fees for such countries. We agreed to purchase a specified percentage of our fidaxomic product requirements for North America and Europe from Patheon or its affiliates.

In February 2011, we entered into a collaboration and license agreement with APEL pursuant to which we granted to APEL an exclusive, royalty-bearing license under certain of our know-how and intellectual property to develop and commercialize fidaxomicin in the APEL territories. Under the terms of the license agreement, APEL paid to us an up-front fee of \$69.2 million in March 2011 and we recognized a milestone payment of 40.0 million Euros in December 2011 as the result of APEL attaining EMA approval of DIFICLIR. APEL paid us 50.0 million Euros in June 2012 which consisted of the 40.0 million Euro approval milestone payment and a 10.0 million Euro milestone for the first commercial launch of DIFICLIR in the APEL territories. We are eligible to receive additional cash payments totaling up to 65.0 million Euros upon the achievement by APEL of specified commercial milestones. In addition, we are entitled to receive escalating double-digit royalties ranging from the high-teens to low-twenties on net sales of fidaxomicin products in the APEL territories, which royalties are subject to reduction in certain, limited circumstances. Such royalties are payable by APEL on a product-by-product and country-by-country basis until a generic product accounts for a specified market share of the applicable fidaxomicin product in the applicable country. APEL launched DIFICLIR in Europe during the second quarter of 2012.

In May 2010, we entered into a long-term supply agreement with Biocon Limited, or Biocon, for the commercial manufacture of fidaxomicin's active pharmaceutical ingredient, or API. Pursuant to the agreement, Biocon agreed to manufacture and supply to us, up to certain limits, fidaxomicin API and, subject to certain conditions, we agreed to purchase from Biocon at least a portion of our requirements for fidaxomicin API in the United States and Canada. We previously paid Biocon \$2.5 million for certain equipment purchases and manufacturing scale-up activities, and we are entitled to recover up to \$1.5 million of this amount, under the supply agreement, in the form of discounted prices for fidaxomicin API. As of December 31, 2012, we had recovered \$0.9 million of the \$1.5 million.

We may be obligated to make additional payments to Biocon if we fail to meet minimum purchase requirements, following Biocon's dedication of certain manufacturing capacity to the production of fidaxomicin API and if Biocon is unable to manufacture alternative products with the dedicated capacity.

In February 2007, we repurchased the rights to develop and commercialize DIFICID in North America and Israel from Par under a prospective buy-back agreement. We paid Par a \$5.0 million milestone payment in June 2010 for the successful completion of the second pivotal Phase 3 trial for DIFICID. We are obligated to pay Par a 5% royalty on net sales by us, our affiliates or our licensees of DIFICID in North America and Israel and are obligated to pay a 1.5% royalty on net sales by us or our affiliates of fidaxomicin in the rest of the world. In addition, in the event we license our right to market fidaxomicin in the rest of the world, we will be required to pay Par a 6.25% royalty on net revenues received related to fidaxomicin. We are obligated to pay each of these royalties, on a country-by-country basis, for seven years, commencing on the applicable commercial launch in each such country. In the year ended December 31, 2012, we paid an aggregate of \$8.0 million in royalties to Par.

#### Funding Requirements

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

- our ability to successfully market and sell DIFICID in the United States and Canada and the ability of our collaborators to market other fidaxomicin products in countries outside the United States and Canada;
- the costs of maintaining, growing and managing our commercial infrastructure including our sales and distribution capabilities and the timing of such efforts;
- our decision to conduct future clinical trials, including the design, timing and progress of such clinical trials;
- our ability to establish and maintain strategic collaborations, including licensing and other arrangements;
- the amount and timing of payments we may receive or be required to make under strategic collaborations, including licensing, co-promotion and other arrangements;
- our decision to partner or license fidaxomicin or commercialize fidaxomicin ourselves in countries where we currently do not have a collaboration partner or our own presence;
- the costs of preparing and pursuing applications for regulatory approvals and the timing of such approvals;
- the costs involved in connection with investigating and responding to governmental inquiries related to the issuance of OBI shares to Dr. Michael Chang, the potentially improper payment to the research laboratory and certain related matters described in the Risk Factors and Legal Proceedings sections above, as well as any costs relating to any potential litigation or enforcement proceedings related thereto;
- the costs involved in prosecuting, enforcing or defending patent claims or other intellectual property rights;
- the extent to which we in-license, acquire or invest in other indications, products, technologies and businesses; and
- the ongoing review of strategic alternatives.

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, revenues from sales of DIFICID in the United States and Canada and contract revenues from existing and future collaboration agreements. In addition, we may finance future cash needs through the sale of additional equity securities, new collaboration agreements or debt financing. However, we may not be successful in completing future equity financings, in entering into additional collaboration agreements, in receiving milestone or royalty payments under new or existing collaboration agreements or in obtaining 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.

The capital markets continue to be volatile which has generally made equity and debt financing more difficult to obtain, and may negatively impact our ability to complete financing transactions. Having insufficient funds may require us to delay, scale-back or eliminate some or all of our planned commercialization activities and development programs or negotiate less favorable terms for rights to our products or product candidates 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 debt, 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 do not have any off-balance sheet arrangements.

#### **Contractual Obligations**

The following table describes our long-term contractual obligations and commitments as of December 31, 2012:

		Payments Due by Period								
	Total		Less than 1 year 1-2 years		-2 years	3-5 years		After 5 years		
				· · · · · · · · · · · · · · · · · · ·	(in tho	usands)				
Operating lease obligations	\$	22,345	\$	2,333	\$	5,187	\$	7,709	\$	7,116

Our facilities currently consist of laboratory and office space in San Diego, California, and office space in Jersey City, New Jersey. The lease for our San Diego facility expires in August 2022, subject to two, five-year renewal options. The lease for our facility in Jersey City expires in July 2018, subject to one, five-year renewal option.

We had firm purchase order commitments for the acquisition of inventory from Biocon and Patheon as of December 31, 2012 and 2011 of \$16.3 million and \$1.0 million, respectively.

Pursuant to our co-promotion with Cubist, we are obligated to pay a quarterly fee of \$3.8 million (\$15.0 million per year) beginning in July 2011, the commencement of the sale program of DIFICID in the United States. At December 31, 2012, approximately \$7.5 million of the fee remained to be paid.

The contractual obligations table does not include (a) 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 may develop under our licensing agreement with Cempra in any country which is a member of the Association of Southeast Asian Nations, or ASEAN, or (b) potential future milestone payments of up to \$11.1 million to TSRI due upon achievement of certain clinical milestones, the filing of NDAs or their foreign equivalents and government marketing and distribution approval. We are required to pay royalties on any net sales of fidaxomicin 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.

#### Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Cash Equivalents and Marketable Securities Risk

Our cash, cash equivalents and short-term investments as of December 31, 2012 consisted of money market funds and a U.S. government security. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. 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 10% change in interest rates during the year ended December 31, 2012 would have resulted in an approximately \$18,000 change in net income. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by a sudden change in market interest rates applicable to 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.

Our cash, cash equivalents and short-term investments as of December 31, 2011 consisted primarily of money market funds and United States government instruments and other readily marketable debt instruments. A hypothetical 10% change in interest rates during the year ended December 31, 2011 would have resulted in approximately a \$37,000 change in net loss.

#### Fair Value Measurements

All of our investment securities are available-for-sale securities and are reported on the consolidated balance sheet at market value except for one auction rate preferred security, or ARPS, with a par value of approximately \$1.0 million. As a result of the negative conditions in the global credit markets, our ARPS currently is not liquid. 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 the securities are redeemed by the issuer or they mature.

#### Foreign Currency Risk

While we operate primarily in the United States, we are exposed to foreign currency risk. Our agreement with APEL includes milestone and royalty payments which are denominated in Euros. Our fidaxomicin API manufacturer, Biocon, is located in India and our manufacturer of fidaxomicin tablets, Patheon, is located in Canada. Although we pay Biocon and Patheon in U.S. dollars, changes in the Rupee and the Canadian dollar may result in price adjustments and affect our operating results.

We established subsidiaries in Canada, Optimer Pharmaceuticals Canada, Inc., or Optimer Canada, and in Luxembourg, Optimer Luxembourg 2 S.à.r.l., or Optimer Europe, and we expect Optimer Canada's and Optimer Europe's transactions to be denominated primarily in Canadian dollars and Euros, respectively. As a result, our financial results could be affected by factors such as changes in foreign currency exchange rates or weak economic conditions in foreign markets where we conduct business, including the impact of the existing conditions in the global financial markets in such countries and the impact on both the U.S. dollar, the Canadian dollar and the Euro.

We do not use derivative financial instruments for speculative purposes. We do not engage in exchange rate hedging or hold or issue foreign exchange contracts for trading purposes. Currently, we do not expect the impact of fluctuations in the relative fair value of the other currencies to be material to our results of operations.

## Item 8. Financial Statements and Supplementary Data

Our financial statements required by this item are attached to this Report beginning on page 63.

#### 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**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Exchange Act, and the rules and regulations thereunder, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Exchange Act Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were not effective as of the end of the period covered by this report because of a material weakness in our internal control over financial reporting related to approval of certain non-recurring transactions as discussed below. Notwithstanding the existence of the material weakness described below, management has concluded that the consolidated financial statements included in this report present fairly, in all material respects, our consolidated financial position, results of operations and cash flows for the periods presented in conformity with U.S. generally accepted accounting principles.

#### **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 Exchange Act. 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, 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 statements.

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, 2012. 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. 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 our Audit Committee.

Based on this assessment, management determined that, as of December 31, 2012, our internal control over financial reporting was not 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 because of a material weakness in our internal control over financial reporting related to approval of certain non-recurring transactions. A material weakness is defined as a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

Management concluded that a material weakness existed in our internal control over financial reporting related to approval of certain non-recurring transactions. Management made this determination in February 2013 following a review of our internal control over financial reporting conducted after the independent members of our Board of Directors determined that further remedial action should be taken in light of prior compliance, record keeping and conflict-of-interest issues surrounding the potentially improper payment to a research laboratory and certain related matters.

Ernst & Young LLP, the independent registered public accounting firm that audited our consolidated financial statements included in this annual report, has issued its report on the effectiveness of our internal control over financial reporting as of December 31, 2012.

#### Remediation Efforts to Address Material Weakness

We believe that the steps that we have taken over the past year have remediated the issues that contributed to the material weakness. These steps included the revision of our corporate authorization policy and other compliance policies, the strengthening of our approval procedures, the implementation of training and internal audit procedures to make our compliance and monitoring more comprehensive and changes to our senior management team, concluding with the replacement of our Chief Executive Officer and General Counsel in February 2013. There is no assurance that the remedial steps we have undertaken will be sufficient and additional steps may be necessary to remediate the material weakness identified above.

#### Changes in Internal Control over Financial Reporting

Except as described above, there have been no changes in our internal control over financial reporting in our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited Optimer Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("the COSO criteria"). Optimer Pharmaceuticals, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

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

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

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

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weakness has been identified and included in management's assessment. Management has identified a material weakness related to approval of certain non-recurring transactions. We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Optimer Pharmaceuticals, Inc. as of December 31, 2012 and 2011, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2012. This material weakness was considered in determining the nature, timing and extent of audit tests applied in our audit of the 2012 financial statements and this report does not affect our report dated March 18, 2013, which expressed an unqualified opinion on those financial statements.

In our opinion, because of the effect of the material weakness described above on the achievement of the objectives of the control criteria, Optimer Pharmaceuticals, Inc. has not maintained effective internal control over financial reporting as of December 31, 2012, based on the COSO criteria.

/s/ Ernst & Young LLP

San Diego, California March 18, 2013

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, 2012 pursuant to Regulation 14A, or the Proxy Statement, for our annual meeting of stockholders to be held on May 8, 2013, 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, or the Code, that applies to all officers, directors and employees. The Code 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 Accounting 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, Financial Statement Schedules

1. Financial Statements

See Index to Consolidated Financial Statements in Item 8 of this report.

2. Financial Statement Schedules

None

3. Exhibits

Exhibit No.		Description of Document
3.1	(2)	Optimer Pharmaceuticals, Inc. Amended and Restated Certificate of Incorporation.
3.2	(4)	Amended and Restated Bylaws of Optimer Pharmaceuticals, Inc.
3.3	(16)	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of Optimer
. 3.3	(10)	Pharmaceuticals, Inc.
4.1	(3)	Common Stock Certificate of Optimer Pharmaceuticals, Inc.
4.2	(21)	Stockholder Protection Rights Agreement, dated as of February 26, 2013, between Optimer
		Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, LLC, as Rights Agent, including as Exhibit A the forms of Rights Certificate and of Election to Exercise and as Exhibit B the form of Certificate of Designation and Terms of the Participating Preferred Stock of the Company.
10.1	(1)*	Master Services Agreement between Optimer Pharmaceuticals, Inc. and Advanced Biologics, LLC (subsequently INC Research, Inc.), dated November 16, 2005, as amended.
10.2	(1)*	License Agreement between Optimer Pharmaceuticals, Inc. and The Scripps Research Institute, dated July 23, 1999.
10.3	(1)*	License Agreement between Optimer Pharmaceuticals, Inc. and The Scripps Research Institute, dated May 30, 2001.
10.4	(1)+	Form of Employee Proprietary Information Agreement of Optimer Pharmaceuticals, Inc.
10.5	(1)+	Offer letter between Optimer Pharmaceuticals, Inc. and Sherwood L. Gorbach, dated October 6, 2005.
10.6	(1)+	Form of Indemnification Agreement between Optimer Pharmaceuticals, Inc. and its directors and officers.
10.7	(1)+	1998 Stock Plan of Optimer Pharmaceuticals, Inc.
10.8	(1)+	Stock Plan Stock Option Agreement of Optimer Pharmaceuticals, Inc.
10.9	(10)+	2006 Equity Incentive Plan of Optimer Pharmaceuticals, Inc., as amended.
10.10	(4)+	Employee Stock Purchase Plan of Optimer Pharmaceuticals, Inc., as amended.
10.11	(2)	Prospective Buy-Back Agreement between Optimer Pharmaceuticals, Inc. and Par Pharmaceutical, Inc., dated January 19, 2007.
10.12	(5)*	Collaboration Research and Development and License Agreement between Optimer
10.12	(5)*	Pharmaceuticals, Inc. and Cempra Pharmaceuticals, Inc., dated March 31, 2006, as amended. Intellectual Property Assignment and License Agreement between Optimer Pharmaceuticals, Inc. and
		Optimer Biotechnology, Inc., dated October 30, 2009.  Offer letter between Optimer Pharmaceuticals, Inc. and Pedro Lichtinger, dated May 5, 2010.
10.14	(6)+	
10.15	(8)+	Offer letter between Optimer Pharmaceuticals, Inc. and Kurt Hartman, dated November 12, 2010.
10.16	(7)*	API Manufacturing and Supply Agreement between Optimer Pharmaceuticals, Inc. and Biocon Limited, dated May 18, 2010.
10.17	(8)+	Offer letter between Optimer Pharmaceuticals, Inc. and Linda Amper, dated January 18, 2011.
10.18	(13)+	Optimer Pharmaceuticals, Inc. Amended and Restated Severance Benefit Plan.
10.19	(8)	Amendment to API Manufacturing and Supply Agreement between Optimer Pharmaceuticals, Inc. and Biocon Limited, dated December 21, 2010.
10.20	(8)	Office Lease between Optimer Pharmaceuticals, Inc. and 101 Hudson Leasing Associates, dated February 9, 2011.
10.21	(9)*	Collaboration and License Agreement between Optimer Pharmaceuticals, Inc. and Astellas Pharma Europe Ltd., dated February 2, 2011.
10.22	(9)*	Supply Agreement between Optimer Pharmaceuticals, Inc. and Astellas Pharma Europe Ltd., dated February 2, 2011.
10.23	(13)	Optimer Pharmaceuticals, Inc. Incentive Compensation Plan.
10.24	(11)	Amendment Agreement between Optimer Pharmaceuticals, Inc. and Astellas Pharma Europe, Ltd., dated March 29, 2011.
10.25	(11)*	Co-Promotion Agreement between Optimer Pharmaceuticals, Inc. and Cubist Pharmaceuticals, Inc., dated April 5, 2011.
10.26	(11)	First Amendment to Lease between Optimer Pharmaceuticals, Inc. and 101 Hudson Leasing Associates, dated May 4, 2011.
10.27	(11)*	Manufacturing Services Agreement between Optimer Pharmaceuticals, Inc. and Patheon Inc., dated June 1, 2011.
10.28	(11)+	2006 Equity Incentive Plan Form of Notice of Grant of Restricted Stock Units.
10.29	(12)	Second Amendment to Lease between Optimer Pharmaceuticals, Inc. and 101 Hudson Leasing Associates, dated July 5, 2011.
10.30	(12)	Third Amendment to Lease between Optimer Pharmaceuticals, Inc. and 101 Hudson Leasing Associates, dated September 30, 2011.
10.31	(14)	Lease Agreement between Optimer Pharmaceuticals, Inc. and ARE-SD Region No. 33, LLC, dated

		December 15, 2011.
10.32	(15)*	Collaboration and License Agreement between Optimer Pharmaceuticals, Inc. and Astellas Pharma Inc., dated March 29, 2012.
10.33	(15)*	Supply Agreement between Optimer Luxembourg 2 S.à.r.l. and Astellas Pharma Inc., dated March 29, 2012.
10.34	(15)	Letter of Agreement between Optimer Pharmaceuticals, Inc. and Optimer Biotechnology, Inc. dated January 31, 2012.
10.35	(16)+	Optimer Pharmaceuticals, Inc. 2012 Incentive Plan.
10.36	(17)+	Offer letter between Optimer Pharmaceuticals, Inc. and Stephen W. Webster dated May 30, 2012.
10.37	(18)*	Second Amendment to API Manufacturing and Supply Agreement between Optimer Pharmaceuticals, Inc. and Biocon Limited, dated May 20, 2011.
10.38	(18)+	Form of Option Grant Notice and Agreement under 2012 Equity Incentive Plan.
10.39	(18)+	Form of Employee Restricted Stock Unit Notice and Agreement under 2012 Equity Incentive Plan.
10.40	(18)+	Form of Director Restricted Stock Unit Notice and Agreement under 2012 Equity Incentive Plan.
10.41	(19)	First Amendment to Collaboration and License Agreement between Optimer Pharmaceuticals, Inc. and Astellas Pharma Europe, Ltd., dated September 6, 2012.
10.42	(19)	Third Amendment to API Manufacturing and Supply Agreement between Optimer Pharmaceuticals, Inc. and Biocon Limited, dated September 10, 2012.
10.43	(20)+	Optimer Pharmaceuticals, Inc. 2012 Equity Incentive Plan, as amended, dated November 2, 2012
10.44	, ,	Stock Purchase Agreement by and among Optimer Pharmaceuticals, Inc. and certain investors listed therein dated October 5, 2012.
10.45	*	Supplemental Agreement Regarding Intellectual Property Assignment and License Agreement by and between Optimer Pharmaceuticals, Inc. and Optimer Biotechnology, Inc. dated October 19, 2012.
10.46	+	Separation Agreement between Optimer Pharmaceuticals, Inc. and Gregory Papaz dated January 22, 2013.
10.47	(21)+	Letter Agreement, dated February 26, 2013, by and between Pedro Lichtinger and Optimer Pharmaceuticals, Inc.
10.48	(21)+	Letter Agreement, dated February 26, 2013, by and between Kurt Hartman and Optimer Pharmaceuticals, Inc.
10.49	+	Separation Agreement between Optimer Pharmaceuticals, Inc. and Kurt Hartman executed March 2, 2013.
21.1		Subsidiaries of Optimer Pharmaceuticals, Inc.
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).
101.INS		XBRL Instance Document
101.SCH		XBRL Taxonomy Extension Schema Document
101.CAL		XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF		XBRL Taxonomy Extension Definition Linkbase Document
101.LAB		XBRL Taxonomy Extension Label Linkbase Document
101.PRE		XBRL Taxonomy Extension Presentation Linkbase Document

Indicates management contract or compensatory plan.

- Filed with Registrant's Registration Statement on Form S-1 on November 9, 2006. (1)
- Filed with Registrant's Amendment No. 3 to Registration Statement on Form S-1 on January 22, 2007. (2)
- Filed with Registrant's Amendment No. 4 to Registration Statement on Form S-1 on February 5, 2007. (3)
- Filed with the Registrant's Current Report on Form 8-K on September 18, 2007.
- (4) (5) Filed with the Registrant's Quarterly Report on Form 10-Q on November 3, 2009.
- (6) Filed with the Registrant's Current Report on Form 8-K on May 6, 2010.
- Filed with the Registrant's Quarterly Report on Form 10-Q on August 4, 2010. (7)
- (8) Filed with the Registrant's Annual Report on Form 10-K on March 10, 2011.
- Filed with the Registrant's Quarterly Report on Form 10-Q on May 6, 2011.
- (9) (10)Filed with the Registrant's Current Report on Form 8-K on June 10, 2011.
- Filed with the Registrant's Quarterly Report on Form 10-Q on August 4, 2011. (11)
- (12)Filed with the Registrant's Quarterly Report on Form 10-Q on November 3, 2011.
- Filed with the Registrant's Current Report on Form 8-K on February 13, 2012. (13)
- (14) Filed with the Registrant's Annual Report on Form 10-K on March 8, 2012.

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.

- (15) (16) (17)

- Filed with the Registrant's Quarterly Report on Form 10-Q on May 10, 2012. Filed with the Registrant's Current Report on Form 8-K on May 10, 2012. Filed with the Registrant's Current Report on Form 8-K on June 5, 2012. Filed with the Registrant's Quarterly Report on Form 10-Q on August 3, 2012. Filed with the Registrant's Current Report on Form 8-K on November 2, 2012. Filed with the Registrant's Current Report on Form 8-K on November 7, 2012.
- (18) (19) (20)
- Filed with the Registrant's Current Report on Form 8-K on February 27, 2013. (21)

#### **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, INC.

Dated: March 18, 2013	By:	/s/ Henry A. McKinnell	
	Name:	Henry A. McKinnell	
	Title:	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/ HENRY A. MCKINNELL Henry A. McKinnell	Chief Executive Officer and Chairman (Principal Executive Officer)	March 18, 2013
/s/ STEPHEN W. WEBSTER Stephen W. Webster	Chief Financial Officer (Principal Accounting and Financial Officer)	March 18, 2013
/s/ ANTHONY E. ALTIG Anthony E. Altig	Director	March 18, 2013
/s/ MARK AUERBACH Mark Auerbach	Director	March 15, 2013
/s/ JOSEPH Y. CHANG Joseph Y. Chang	Director	March 15, 2013
/s/ PETER E. GREBOW PETER E. GREBOW	Director	March 15, 2013
/s/ STEPHEN L. NEWMAN Stephen L. Newman	Director	March 15, 2013
/s/ ROBERT L. ZERBE Robert L. Zerbe	Director	March 15, 2013

## Item 8. Financial Statements and Supplementary Data

## INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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#### 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, 2012 and 2011, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity and cash flows for each of the three years in the period ended December 31, 2012. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Optimer Pharmaceuticals, Inc. at December 31, 2012 and 2011, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Optimer Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 18, 2013 expressed an adverse opinion thereon.

/s/ ERNST & YOUNG LLP

San Diego, California March 18, 2013

## Optimer Pharmaceuticals, Inc. Consolidated Balance Sheets

	December 31,			l <b>.</b>
		2012		2011
ASSETS				
Current assets:				04 505 510
Cash and cash equivalents	\$	119,444,586	\$	31,787,512
Short-term investments		4,556,329		78,791,066
Trade accounts receivable, net		7,119,089		6,563,645
Accounts receivable, other		2,391,071		52,289,290
Inventory		15,061,771		3,947,380
Prepaid expenses and other current assets		3,442,717		3,781,830
Total current assets		152,015,563	. !	177,160,723
Property, equipment and other, net		4,338,720		2,590,715
Long-term investment		820,000	1	882,000
Deferred tax assets, non-current		890,843	- 1	_
Other assets		1,362,196		1,389,734
Total assets	\$	159,427,322	\$_	182,023,172
Total assets				
LIABILITIES AND STOCKHOLDERS' EQUITY			1	
Current liabilities:				
Accounts payable	\$	7,166,127	\$	9,860,462
Accrued liabilities		19,165,362		21,447,544
Deferred revenue		456,250		
Total current liabilities		26,787,739		31,308,006
Deferred rent		938,520		151,141
Income taxes payable, non-current		890,843		
Commitments and contingencies		· —		
Stockholders' equity:				
Preferred stock, \$0.001 par value, 10,000,000 shares authorized and no shares issued and				
outstanding at December 31, 2012 and 2011, respectively				
Common stock, \$0.001 par value, 150,000,000 shares and 75,000,000 shares authorized at		•		
December 31, 2012 and December 31, 2011, respectively, 47,791,531 shares and				
46,689,951 shares issued and outstanding at December 31, 2012 and 2011,			. :	
respectively		47,792		46,690
Additional paid-in capital		382,277,671		358,895,471
Accumulated other comprehensive income (loss)		464,170		(46,725)
Accumulated deficit		(251,979,413)		(214,992,783)
Total Optimer Pharmaceuticals, Inc. stockholders' equity	_	130,810,220		143,902,653
Total Optimer Pharmaceuticals, Inc. stockholders equity				6,661,372
Non-controlling interest	_	130,810,220	_	150,564,025
Total stockholders' equity	<u> </u>	159,427,322	\$	182,023,172
Total liabilities and stockholders' equity	<u>\$</u>	137,741,344	=	102,023,172

## Optimer Pharmaceuticals, Inc. Consolidated Statements of Operations

	Years Ended December 31,					
		2012		2011		2010
Revenues:						
Product sales, net	\$	62,417,155	\$	21,511,037	\$	
Contract revenue	•	39,112,168	Ť.	122,749,000	•	
Other		2,106		718,336		1,480,362
Total revenues		101,531,429		144,978,373		1,480,362
Cost and expenses:		, , , , , , , , , , , , , , , , , , , ,				1, . 0 0,000
Cost of product sales		5,486,239		1,525,798		
Cost of contract revenue		6,462,939		7,584,353		
Research and development		45,202,722		43,085,307		32,797,672
Selling, general and administrative		112,025,724		80,574,336		17,550,883
Co-promotion expenses with Cubist		23,190,629		6,569,921		
Total operating expenses		192,368,253		139,339,715		50,348,555
Income (loss) from operations		(90,836,824)		5,638,658		(48,868,193)
Gain on de-consolidation of OBI		23,782,229		· · · —		
Gain of sale of OBI shares		31,500,606				
Equity in net loss of OBI		(1,849,254)				
Interest income and other, net		136,269		290,870		329,290
Consolidated net income (loss)		(37,266,974)		5,929,528		(48,538,903)
Net loss attributable to noncontrolling interest		280,344		1,892,096		1,199,161
Net income (loss) attributable to Optimer Pharmaceuticals, Inc	\$	(36,986,630)	\$	7,821,624	\$	(47,339,742)
Net income (loss) per share attributable to Optimer Pharmaceuticals, Inc.						
common stockholders - basic	\$	(0.78)	\$	0.17	\$	(1.25)
Net income (loss) per share attributable to Optimer Pharmaceuticals, Inc.			÷		-	(1.26)
common stockholders - diluted	\$	(0.78)	\$	0.17	\$	(1.25)
Shares used to compute net income (loss) per share attributable to	Ψ	(0.78)	<u> </u>	0.17	9	(1.25)
common stockholders - basic		47 221 510		45 (22 169		27 920 450
		47,331,510		45,622,168		37,830,452
Shares used to compute net income (loss) per share attributable to		48 004 540		1.2		
common stockholders - diluted	-	47,331,510		46,500,269	-	37,830,452

## Optimer Pharmaceuticals, Inc. Consolidated Statements of Comprehensive Income (Loss)

	Years Ended December 31,			
	2012	2011	2010	
Consolidated net income (loss)	\$ (37,266,974)	\$ 5,929,528	\$ (48,538,903)	
Other comprehensive income (loss): Change in foreign currency translation adjustment	(78,320)	(594,553)	419,516	
Unrealized gains (losses) on securities: Unrealized gains (losses) during period, net of tax	589,215	119,789	(3,020)	
Reclassification adjustment for net gains included in net income  Net unrealized gains (losses) on securities	589,215	119,789	(3,020)	
Total other comprehensive income (loss)	\$\frac{510,895}{\\$ (36,756,079)}	(474,764) \$ 5,454,764	416,496 \$ (48,122,407)	

## Optimer Pharmaceuticals, Inc. Consolidated Statements of Stockholders' Equity

	_				Accumulated Other			
	Commo Shares	on Stock Amount	Ac	lditional Paid- in-Capital	Comprehensive	Accumulated	Non-controlling	
Balance at December 31, 2009	33,139,373	\$ 33,139	\$	205,114,914	Income (Loss)	Deficit (175 474 665)	Interest	Total
Issuance of common stock upon exercise of options	552,253	φ 55,159 552		1,171,550	\$ 38,063	\$ (175,474,665)	\$ 3,040,156	
Issuance of common stock during the public offerings, net	332,233	332		1,1/1,330	_	<del>-</del>	<del></del>	1,172,102
	4,887,500	4,888		51,203,837				
Issuance of common stock pursuant to employee stock	4,007,500	4,000		31,203,837			-	51,208,725
purchase plan	49,077	40		400 401				
Issuance of common stock for consulting services	585,762	49		422,481	_	_	_	422,530
Compensation expense related to grants of consultant stock	363,762	586		3,377,331	_			3,377,917
options and awards	CE 000							
Employee stock-based compensation	65,000	65		2,121,984	_	_	_	2,122,049
				4,253,635	_		_	4,253,635
Unrealized loss on short-term investment	_	_			(3,020)	<del></del>		(3,020)
Foreign currency translation adjustment	*			_	263,807		155,709	419,516
Net loss						(47,339,742)	(1,199,161)	(48,538,903)
Balance at December 31, 2010	39,278,965	39,279		267,665,732	298,850	(222,814,407)	1,996,704	47,186,158
Issuance of common stock upon exercise of options	347,803	347		1,858,738		`	· · · —	1,859,085
Issuance of common stock during the public offerings, net								-,,
	6,900,000	6,900		73,151,057		_	_	73,157,957
Issuance of common stock pursuant to employee stock								,,
purchase plan	71,650	72		640,150			_	640,222
Issuance of common stock upon exercise of warrants	91,533	92		999,907	_		_	999,999
Issuance of common stock for consulting services and				,				777,777
other	_	_		2,793,513	_	· · · · · · · · · · · · · · · · · · ·	491,761	3,285,274
Employee stock-based compensation		_		11,786,374	<u></u>	_	451,701	11,786,374
Sale of subsidiary common stock to non-controlling				11,700,571		<del></del>		11,700,374
interest				_		•	6,194,192	6,194,192
Unrealized gain on short-term investment	_			_	119,789		0,194,192	
Foreign currency translation adjustment	_				(465,364)	<del>_</del>	(129,189)	119,789
Net income		·			(403,304)	7 921 624		(594,553)
Balance at December 31, 2011	46,689,951	46,690		358,895,471	(46.705)	7,821,624	(1,892,096)	5,929,528
Issuance of common stock upon exercise of options and	40,009,931	40,090		336,693,471	(46,725)	(214,992,783)	6,661,372	150,564,025
lapse of restricted stock								
units	641,476	641		5 204 112				
Issuance of common stock pursuant to employee stock	071,470	041		5,394,112	_			5,394,753
purchase plan	172 044	100		1 406 004				
Issuance of common stock for consulting services and	173,844	175		1,486,894	_		_	1,487,069
other	206.260	204				***		
Employee stock-based compensation	286,260	286		3,792,710		. <del>-</del>	_	3,792,996
De-consolidation of OBI	_	******		12,708,484				12,708,484
Net unrealized gain on short-term	_	_		_	_		(6,381,028)	(6,381,028)
investment		_		_	589,215	•	_	589,215
Foreign currency translation adjustment		_		_	(78,320)	_	_	(78,320)
Net loss						(36,986,630)	(280,344)	(37,266,974)
Balance at December 31, 2012	47,791,531	\$ 47,792	\$	382,277,671	\$ 464,170	\$ (251,979,413)	<u> </u>	\$ 130,810,220

## Optimer Pharmaceuticals, Inc. Consolidated Statements of Cash Flows

	Years Ended December 31,			
	2012	2011	2010	
Operating activities:	* (0=0<< 0=1)	A 5 000 500	φ (40.520.003)	
Net income (loss)	\$ (37,266,974)	\$ 5,929,528	\$ (48,538,903)	
Adjustments to reconcile net income (loss) to net cash provided (used)				
in operating activities:			206 510	
Depreciation and amortization	877,205	525,008	306,718	
Stock-based compensation	12,708,484	11,786,374	6,375,684	
Issuance of common stock for consulting services and other	3,792,996	3,285,274	3,377,917	
Deferred rent	787,109	10,003	(112,336)	
Deferred tax assets	(890,843)	-	_	
Gain on de-consolidation of OBI	(23,782,229)		<del>-</del>	
Gain on sales of OBI shares	(31,500,606)		<del></del>	
Equity in net loss of OBI	1,849,254			
(Gain) Loss on disposal of assets	(35,401)	21,681	(25,511)	
Impairment of long-term security	62,000		<del></del>	
Tax provision	(281,147)			
Changes in operating assets and liabilities:				
Trade accounts receivable, net	(555,444)	(6,563,645)		
Accounts receivable, other	49,679,755	(52,289,290)	30,612	
Inventory	(11,114,391)	(3,947,380)		
Prepaid expenses and other current assets	(2,248,356)	(3,264,971)	(130,612)	
Other assets	(39,594)	(881,544)	(9,428)	
Accounts payable and accrued expenses	(2,273,493)	26,615,140	(2,958,043)	
Deferred revenues	456,250	_		
Income tax payable	890,843			
Net cash used by operating activities	(38,884,582)	(18,773,822)	(41,683,902)	
Investing activities:				
Purchases of short-term investments	(3,798,622)	(91,279,751)	(55,284,340)	
Sales or maturities of short-term investments	68,535,682	42,165,000	46,845,000	
Purchases of property and equipment	(2,900,588)	(2,439,718)	(305,992)	
Proceeds from sale of fixed assets	83,500	_		
Reduction of cash due to de-consolidation of OBI	(4,010,680)		_	
Purchase of OBI shares	(468,748)	_		
Proceeds from sale of OBI common stock	61,847,075			
Net cash provided (used) by investing activities	119,287,619	(51,554,469)	(8,745,332)	
Financing activities:				
Proceeds from sale of common stock	6,881,822	76,657,262	52,803,357	
Proceeds from sale of subsidiary common stock		6,194,192		
Net cash provided by financing activities	6,881,822	82,851,454	52,803,357	
Effect of exchange rate changes on cash and cash equivalents	372,215	(597,575)	433,473	
Net increase in cash and cash equivalents	87,657,074	11,925,588	2,807,596	
Cash and cash equivalents at beginning of period	31,787,512	19,861,924	17,054,328	
Cash and cash equivalents at end of period	\$ 119,444,586	\$ 31,787,512	\$ 19,861,924	
oner and cross offer, events at the control of beautiful and and an event and an ev		·		
Supplemental disclosure of cash flow information:				
Purchase of fixed assets by incurring current liabilities	\$ 571,261			

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 1. Organization and Summary of Significant Accounting Policies

Optimer Pharmaceuticals, Inc. ("Optimer" or the "Company") is a global biopharmaceutical company focused on commercializing innovative hospital specialty products. The Company currently markets one product in the United States and Canada, DIFICID® (fidaxomicin) tablets. DIFICID is a macrolide antibacterial drug that is approved in the United States for the treatment of Clostridium difficile-associated diarrhea ("CDAD") in adults. CDAD is the most common symptom of Clostridium difficile infection ("CDI"). DIFICID is approved in Canada for the treatment of CDI. Fidaxomicin also is approved in Europe for the treatment of CDI, where it is marketed by a licensee as DIFICLIR™. Optimer is pursuing commercialization in other territories through collaboration partners and is progressing with life-cycle management initiatives for fidaxomicin.

#### Principles of Consolidation

The consolidated financial statements include all the accounts of the Company and its wholly-owned subsidiaries. Prior to February 7, 2012, Optimer Biotechnology Inc. ("OBI") was consolidated for financial reporting purposes. All intercompany balances and transactions have been eliminated in consolidation. During the three month period ending March 31, 2012, the Company reduced its ownership interest in OBI from a majority interest to a 43% interest. As a result, the Company deconsolidated OBI as of February 7, 2012 and derecognized the OBI assets, liabilities, and noncontrolling interest from its financial statements. Management applied deconsolidation accounting guidance, which included analyzing the Company's investment in OBI at February 7, 2012 to determine the fair value on the date of deconsolidation and the related gain or loss upon deconsolidation. The Company subsequently sold OBI in October 2012 (see Note 9).

#### 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. Except for one auction rate preferred security ("ARPS"), 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 income/(loss). 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. At December 31, 2012, cash, cash equivalents and short-term investments totaled approximately \$124.0 million.

#### 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.

The Company's accounts receivable consist of amounts due from customers for the sales of DIFICID in the United States and Canada. The following table sets forth the percentage of our gross product sales to distribution customers who represented 10% or more of gross product sales in 2012 and 2011 and accounts receivable related to such customers for the years ended December 31, 2012 and 2011:

	Gross Product Sales		Accounts Receivable	
	2012	2011	2012	2011
AmerisourceBergen Corporation	22%	23%	17%	21%
Cardinal Health, Inc	36%	43%	39%	30%
McKesson Corporation	35%	30%	37%	46%
	93%	96%	93%	97%

### Accounts Receivable

Trade accounts receivable are recorded net of reserves for estimated prompt-payment discounts, service fee arrangements and any allowance for doubtful accounts. Reserves for other sales-related allowances such as rebates, distribution and other fees, and product returns are included in accrued expenses in the Company's consolidated balance sheets. The allowance for prompt-pay discounts and service fees was \$1.9 million and \$1.6 million at December 31, 2012 and 2011, respectively.

### Inventory

Inventory is stated at the lower of cost or market. Cost is determined using the first-in, first-out ("FIFO") method. The Company reserves for potentially excess, dated or obsolete inventories based on an analysis of inventory on hand compared to forecasts of future sales. Net inventory consisted of the following, as of the dates indicated:

	December 31,						
		2012	1	2011			
Raw materials	\$	9,072,123	\$	1,815,696			
Work in process		3,552,169		1,321,763			
Finished goods		2,923,541		809,921			
	\$	15,547,833	\$	3,947,380			
Reserves		(486,062)		·			
	\$	15,061,771	\$	3,947,380			

### Foreign Currency Translation

The functional currency for the Company's Canadian subsidiary is the local currency. Assets and liabilities denominated in foreign currencies are translated using the exchange rates on the balance sheet dates. Net revenues and expenses are translated using the average exchange rates prevailing during the year. Any translation adjustments resulting from this process are shown separately as a component of accumulated other comprehensive income (loss) within stockholders' equity in the consolidated balance sheets. Foreign currency transaction gains and losses are reported net in the consolidated statements of operations.

### Fair Value Measurements

The carrying amount of cash and cash equivalents, accounts receivable, prepaid expenses, other current assets, 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 quoted market prices for those securities.

# 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.

# Impairment 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. Assets and liabilities that are part of a disposed group and classified as held for sale would be presented separately in the appropriate asset and liability sections of the balance sheet. The Company has not recognized any impairment losses through December 31, 2012.

# 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.

### 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.

#### Net Product Sales

DIFICID is available in the United States and Canada through three major wholesalers - AmerisourceBergen Corporation, Cardinal Health, Inc. and McKesson Corporation - and through regional wholesalers and specialty pharmacies that provide DIFICID to purchasing customers, such as hospitals, retail pharmacies, long-term care facilities and other purchasing outlets that may dispense DIFICID. The Company recognizes revenue from product sales when persuasive evidence of an arrangement exists, delivery has occurred, title has passed to the customer, the price is fixed and determinable, the buyer is obligated to pay the Company, the obligation to pay is not contingent on resale of the product, the buyer has economic substance apart from the Company, the Company has no obligation to bring about the sale of the product, the amount of returns can be reasonably estimated and collectability is reasonably assured. The Company recognizes product sales of DIFICID upon delivery of product to the wholesalers, specialty pharmacies and certain direct purchasers.

The Company's net product sales represent total gross product sales in the United States and Canada less allowances for customer credits, including estimated rebates, chargebacks, discounts and returns. These allowances are established by management as its best estimate, based on available information, and are adjusted to reflect known changes in the factors that impact such allowances. Allowances for rebates, chargebacks, discounts and returns are established based on the contractual terms with customers, communications with customers, as well as expectations about the market for the product and anticipated introduction of competitive products. Product shipping and handling costs are included in cost of sales.

Product Sales Allowances. The Company establishes reserves for prompt-payment discounts, fee-for-service arrangements, government and commercial rebates, product returns and other applicable allowances, such as the Company's hospital discount. Allowances relate to prompt-payment discounts and fee-for-service arrangement with the Company's contracted wholesalers and direct purchase discounts, and are recorded at the time of sale, resulting in a reduction in product sales revenue. Accruals related to government and commercial rebates, product returns and other applicable allowances are recognized at the time of sale, resulting in a reduction in product sales and an increase in accrued expenses.

Prompt-payment Discounts. The Company offers a prompt-payment discount to its customers. Since the Company expects its customers will take advantage of this discount, the Company accrues 100% of the prompt-payment discount that is based on the gross amount of each invoice, at the time of sale. The accrual is adjusted quarterly to reflect actual earned discounts.

Government and Commercial Rebates and Chargebacks. The Company estimates commercial rebates as well as government-mandated rebates and discounts relating to federal and state programs such as Medicaid, the Veterans' Administration, or VA, and Department of Defense programs, the Medicare Part D Coverage Discount Program and certain other qualifying federal and state government programs. The Company estimates the amount of these rebates and chargebacks based on historical trends for DIFICID. These allowances are adjusted each period based on actual experience.

Medicaid rebate reserves relate to the Company's estimated obligations to states under statutory "best price" obligations which also may include supplemental rebate agreements with certain states. Rebate accruals are recorded during the same period in which the related product sales are recognized. Actual rebate amounts are determined at the time of claim by the state, and the Company generally will make cash payments for such amounts after receiving billings from the state.

VA rebates or chargeback reserves represent the Company's estimated obligations resulting from contractual commitments to sell DIFICID to qualified healthcare providers at a price lower than the list price charged to the Company's distributors. A distributor will charge the Company for the difference between what the distributor pays for the product and the ultimate selling price to the qualified healthcare provider. Rebate and chargeback accruals are established during the same period in which the related product sales are recognized. Actual chargeback amounts for Public Health Service are determined at the time of resale to the qualified healthcare provider from the distributor, and the Company generally will issue credits for such amounts after receiving notification from the distributor.

Although allowances and accruals are recorded at the time of product sale, certain rebates generally will be paid, on average, in six months or longer after the sale. Reserve estimates are evaluated quarterly and, if necessary, adjusted to reflect actual results. Any such adjustments will be reflected in the Company's operating results in the period of the adjustment. For the year ended December 31, 2012, there were no material adjustments.

Product Returns. The Company's policy in the United States is to accept returns of DIFICID for six months prior to, and twelve months after, the product expiration date. The Company's policy in Canada is to accept returns of DIFICID for three months prior to, and twelve months after, the product expiration date. The Company permits returns if the product is damaged or defective when received by its customers. The Company will provide a credit for such returns to customers with whom it has a direct relationship. Once product is dispensed it cannot be returned, but the Company allows partial returns in states where such returns are mandated. The Company does not exchange product from inventory for the returned product.

Allowances for product returns are recorded during the period in which the related product sales are recognized, resulting in a reduction to product revenue. The Company estimates product returns based upon the sales pattern of DIFICID, management's experience with similar products, historical trends in the pharmaceutical industry and trends for similar products sold by others.

During the years ended December 31, 2012 and 2011, the provisions for product sales allowances reduced gross product sales as follows:

Total gross product sales	\$	<b>2012 74,890,803</b>	\$	2011 24,357,200
Returns reserve and allowances  Government and commercial rebates and chargebacks  Prompt-pay discounts and fees  Product sales allowance  Total product sales, net	\$ \$	(1,583,723) (4,947,295) (5,942,630) (12,473,648) 62,417,155	\$_ \$_	(365,358) (476,116) (2,004,689) (2,846,163) 21,511,037
Total product sales allowances as a percent of gross product sales	_	16.7%		11.7%

An analysis of the amount of, and change in, reserves for the years ended December 31, 2012 and 2011 is as follows:

	Resei	urns ve and vances	Com Reba	ernment and amercial ates and gebacks	Di	mpt-pay scounts nd Fees		Total
Balance at January 1, 2011	\$		\$		\$		\$	
Provisions related to sales in the current year	. 3	65,358		476,116	2	,004,689	•	2,846,163
Returns and payments		·	. (	106,218)		(429,403)		(535,621)
Balance at December 31, 2011	3	65,358		369,898	1	,575,286		2,310,542
Provisions related to sales in the current year	1,5	83,723	4,	988,805	5	,953,674		12,526,202
Provisions related to sales made in prior year				(41,510)		(11,044)		(52,554)
Returns and payments	(4	73,957)	(3,	674,344)	(5	,629,393)		(9,777,694)
Balance at December 31, 2012	\$ 1,4	75,124	\$ 1,	642,849	\$ 1	,888,523	\$	5,006,496

# Contract Revenue

Under certain of the Company's licensing and collaboration agreements, it is entitled to receive payments upon the achievement of contingent milestone events. In order to determine the revenue recognition for contingent milestone-based payments, the Company evaluates the contingent milestones using the criteria as provided by the Financial Accounting Standards Boards, or FASB, guidance on the milestone method of revenue recognition at the inception of a collaboration agreement.

Accounting Standard Codification (ASC) Topic 605-28, Revenue Recognition — Milestone Method (ASC 605-28), established the milestone method as an acceptable method of revenue recognition for certain contingent, event-based payments under

research and development arrangements. Under the milestone method, a payment that is contingent upon the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. A milestone is an event (i) that can be achieved based in whole or in part on either the Company's performance or on the occurrence of a specific outcome resulting from the Company's performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due to the Company. The determination that a milestone is substantive is judgmental and is made at the inception of the arrangement. Milestones are considered substantive when the consideration earned from the achievement of the milestone is (i) commensurate with either the Company's performance to achieve the milestone, (ii) relates solely to past performance and (iii) is reasonable relative to all deliverables and payment terms in the arrangement.

Other contingent, event-based payments received for which payment is either contingent solely upon the passage of time or the results of a collaborative partner's performance are not considered milestones under ASC 605-28. In accordance with ASC Topic 605-25, Revenue Recognition — Multiple-Element Arrangements (ASC 605-25), such payments will be recognized as revenue when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the price is fixed or determinable; and collectability is reasonably assured.

Revenues recognized for royalty payments are recognized as earned in accordance with the terms of various research and collaboration agreements.

For collaboration agreements with multiple deliverables, the Company recognizes collaboration revenues and expenses by analyzing each element of the agreement to determine if it is to be accounted for as a separate element or single unit of accounting. If an element is to be treated separately for revenue recognition purposes, the revenue recognition principles most appropriate for that element are applied to determine when revenue is to be recognized. If an element is not to be treated separately for revenue recognition purposes, the revenue recognition principles most appropriate for the bundled group of elements are applied to determine when revenue is to be recognized.

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. In connection with certain research collaboration agreements, revenues are recognized from non-refundable up-front fees, that 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.

With respect to revenues derived from reimbursement of direct out-of-pocket expenses for research costs associated with grants, 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 the Company has received from collaborators to date, whether recognized as revenue or deferred, is refundable even if the related program is not successful.

# Research and Development

The Company expenses costs related to research and development as incurred. The Company's research and development expenses consist primarily of license fees, salaries and related employee benefits, costs associated with clinical trials managed by contract research organizations 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. Patent application and administrative costs are recorded as general and administration expenses.

When non-refundable payments for goods or services to be received in the future for use in research and development activities are made, the Company defers and capitalizes these types of payments. The capitalized amounts are expensed when the related goods are delivered or the services are performed.

# Reclassifications

The Company has reclassified certain prior period amounts to conform to the current period presentation. Specifically, in its 2011 Consolidated Statements of Operations, the Company now separately identified its co-promotion expenses with Cubist Pharmaceuticals, Inc. ("Cubist") from selling, general and administrative expenses. This reclassification has no impact on the net loss from operations or stockholder's equity as previously reported.

# Stock-based Compensation

The Company recognizes in its financial statements the share-based payment transactions with employees and consultants based on their fair value and recognized as compensation expense over the vesting period. Compensation expense of \$13.0 million, \$11.8 million and \$6.4 million was recognized in the years ended December 31, 2012, 2011 and 2010, respectively.

Employee 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. Due to the Company's limited history as a commercial entity, the Company used the historical volatility of comparable companies whose share prices are publicly available to estimate the Company's options volatility rate. The average expected term is calculated using the simplified method. 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.

For performance-based stock options and performance-based restricted stock units, the Company begins to recognize the expense when it is deemed probable that the performance-based goal will be met. The Company evaluates the probability of achieving performance-based goals on a quarterly basis.

The Company also grants awards to non-employees and determines the fair value of such stock-based compensation awards granted as either the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable. If the fair value of the equity instruments issued is used, it is measured using the stock price and other measurement assumptions as of the earlier of (i) the date at which a commitment for performance by the counterparty to earn the equity instruments is reached, or (ii) the date at which the counterparty's performance is completed. Equity instruments issued to non-employees are periodically revalued as the equity instruments vest and are recognized as expense over the related service period.

# Comprehensive Income (Loss)

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).

# Investment in OBI

As of the date of de-consolidation, and prior to the sale of its equity interest in OBI, the Company accounted for its investment in OBI under the equity method. The investment was adjusted for Optimer's share in the equity in net loss and cash contributions and distributions for the appropriate periods. In addition, the Company recorded adjustments to reflect the amortization of basis differences attributable to the fair values in excess of net book values of identified tangible and intangible assets.

# Noncontrolling Interest

During 2010 and 2011, the Company owned approximately 60% of the equity interests in OBI. Pursuant to authoritative guidance, the Company accounts and reports for minority interests, the portion of OBI not owned by the Company, as non-controlling interests and classifies them as a component of stockholders' equity on the consolidated balance sheet of the Company. The Company includes the net loss attributable to noncontrolling interests as part of its consolidated net loss.

# Net Income (Loss) per Share Attributable to Common Stockholders

Basic net income (loss) per share attributable to common stockholders is calculated by dividing the net income (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 income (loss) per share attributable to common stockholders is computed by dividing the net income (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, 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,						
	2012	2011	2010				
Historical							
Numerator:							
Net income (loss) attributable to Optimer Pharmaceuticals, Inc.	\$ (36,986,630)	\$ 7,821,624	\$ (47,339,742)				
Denominator:							
Weighted average common shares outstanding - basic	47,331,510	45,622,168	37,830,452				
Effect of dilutive securities:	<del></del>						
Restricted stock		130,586					
Stock award common share equivalents	·	747,515					
Weighted average number of shares of common stock — diluted	47,331,510	46,500,269	37,830,452				
Net income (loss) attributable to common stockholders per share —		: : : : : : : : : : : : : : : : : : :					
basic	\$ (0.78)	\$ 0.17	\$ (1.25)				
Net income (loss) attributable to common stockholders per share —							
diluted	\$ (0.78)	\$ 0.17	\$ (1.25)				
Historical outstanding anti-dilutive securities not included in							
diluted net loss per share calculation							
Common stock options	6,294,574	3,706,708	3,589,626				
Common stock warrants		<del></del>	91,533				
Unvested restricted stock units	372,283	141,000	120,000				
Anticipated shares to be purchased under ESPP	117,636	92,281	28,192				
Total	6,784,493	3,939,989	3,829,351				
		- 7 7-					

# Segment Reporting

The Company's management has determined that it operates in one business segment which is the development and commercialization of pharmaceutical products.

# 2. Fair Value of Financial Instruments

The following tables summarize the Company's financial assets measured at fair value on a recurring basis at December 31, 2012 and 2011:

	Fair Value Measurements at December 31, 2012 Using:						
	Quoted Prices in Active Markets (Level 1)	Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)	Total			
Cash equivalents	\$ 112,609,683	\$	\$ —	\$ 112,609,683			
Marketable security	<u> </u>	3,752,195		3,752,195			
Investment in Cempra	804,134	_		804,134			
Auction rate preferred security			820,000	820,000			
	<u>\$ 113,413,817</u>	\$ 3,752,195	\$ 820,000	\$ 117,986,012			
	Fair	Value Measurements a	nt December 31, 2011 U	sing:			
	Quoted Prices in Active Markets	Observable Inputs (1)	Unobservable Inputs				
Cash equivalents	(Level 1) \$ 26,388,052	(Level 2)	(Level 3)	Total \$ 26,388,052			
Marketable securities	\$ 20,366,032 	78,791,066	<b>.</b>	78,791,066			
Auction rate preferred security	<u></u>	70,771,000	882,000	882,000			
Other assets — forward contracts not designated			:	002,000			
as hedges		1,752,006		1,752,006			
	\$ 26,388,052	\$ 80,543,072	\$ 882,000	\$ 107,813,124			

Level 1: Quoted prices in active markets for identical assets and liabilities; or

Level 2: Quoted prices for identical or similar assets and liabilities in markets that are not active, or observable inputs other than

quoted prices in active markets for identical assets and liabilities; or

Level 3: Unobservable inputs.

Marketable Securities. With the exception of an auction rate security, the Company obtains pricing information from quoted market prices, pricing vendors or quotes from brokers/dealers. The Company conducts reviews of its primary pricing vendors to determine whether the inputs used in the vendors' pricing processes are deemed to be observable. At December 31, 2012 and 2011, the Company's marketable securities consisted primarily of government agency securities. The fair value of government agency securities generally are determined using standard observable inputs, including reported trades, quoted market prices and broker/dealer quotes. These securities are in Level 2.

Investment in Cempra. Equity securities that have readily determinable fair values, not classified as trading securities or as held-to-maturity securities, are classified as available-for-sale securities. Any unrealized gains and losses are reported in other comprehensive income (loss) until realized. In February 2012, Cempra became a publicly-traded company and, as such, the Company assigned a value to the shares it received in March 2006 (see Note 6) and recorded the entire amount as an unrealized gain. The Company considers the equity it owns in Cempra as available-for-sale. The fair value of the Company's investment in Cempra is based on the quoted market price on the reporting date. Cempra's stock is publicly traded and is in Level 1.

Auction Rate Preferred Security. The fair value of the Company's auction rate preferred security is estimated using third-party pricing information or a discounted cash flow model that incorporates transaction details such as contractual terms, maturity and timing and amount of cash flows and the expected holding period of the ARPS. The Company's ARPS is classified as a long-term investment on the consolidated balance sheets, as the Company does not believe it needs to liquidate the security in the near term. The ARPS does not have observable inputs and thus the ARPS is included in Level 3.

As of December 31, 2012, the Company held one ARPS valued at \$820,000 with a perpetual maturity date that resets every 28 days. Although as of December 31, 2012, this ARPS continued to pay interest according to its stated terms, the market in this security continues to be illiquid. In December 2012, based on third-party pricing information, the Company recognized, in the consolidated statement of operations, an unrealized loss of \$62,000 in investment income since the Company had determined that the decline in the value was other-than-temporary.

A reconciliation of the beginning and ending balances of assets measured at fair value on a recurring basis using Level 3 inputs is as follows:

		uction Rate
	<u>Prefe</u>	erred Security
Beginning balance at January 1, 2012	\$	882,000
Total gains and losses:		
Realized net income		. —
Unrealized loss included in interest income and other, net		(62,000)
Purchases, sales, issuances and settlements		. —
Transfers in (out) of Level 3		
Ending balance at December 31, 2012	\$	820,000
Change in unrealized gains (losses) included in net loss related to assets still held	\$	(62,000)

### 3. Short-term Investments

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, upon pricing vendors or upon quotes from brokers/dealers as of the dates presented.

	 December 31, 2012								
	Gross Gross Amortized Unrealized Cost Gains			Gross Unrealized Losses	M	arket Value			
Government agency security	\$ 3,750,198	\$	1,997	\$		\$	3,752,195		
Investment in Cempra			804,134		·		804,134		
	\$ 3,750,198	\$	806,131	\$		\$	4,556,329		

	December 31, 2011							
		Gross Amortized Cost	1	Gross Unrealized Gains		Gross Unrealized Losses	_ 1	Market Value
Government agency securities	\$	69,241,792	\$	106,347	\$	<del></del> .	\$	69,348,139
Corporate bonds		9,429,485		13,442				9,442,927
	\$	78,671,277	\$	119,789	\$		\$	78,791,066

The government agency security did not have an unrealized loss position at December 31, 2012.

In February 2012, Cempra completed its initial public offering, and the Company determined that its equity in Cempra had readily determinable value and recorded the fair value in the Company's books. Prior to February 2012, the Company assigned no value to its equity in Cempra.

The amortized cost and estimated fair value of the security available-for-sale at December 31, 2012, by contractual maturity, are as follows:

	Aı	mortized Cost	Estir	nated Fair Value
Due in one year or less	\$	3,750,198	\$	3,752,195

The weighted average maturity of short-term investments as of December 31, 2012 and 2011, was approximately nine months and seven months, respectively.

Evaluating Investments for Other-than Temporary Impairments

The Company considers a number of factors to determine whether the decline in value in its investments is other-than-temporary, including the length of time and the extent of which the market value has been less than cost, the financial condition of the issuer and the Company's intent to hold and ability to retain these short-term investments. Based on these factors, except for the ARPS, which the Company recorded as an other-than-temporary impairment in 2012 of \$62,000, the Company has not identified any other-than temporary impairment.

### 4. Property and Equipment

Property, equipment and other costs are stated at cost and consist of the following:

		,		
		2012		2011
Equipment	\$	3,072,147	\$	3,098,431
Furniture and fixtures		224,183		226,362
Leasehold improvements		33,761		1,282,138
Computer equipment and software		2,512,512		1,579,514
Construction in progress		427,222		·. —
Organizational costs		55,218		
		6,325,043		6,186,445
Less accumulated depreciation and amortization		(1,986,323)		(3,595,730)
Total property and equipment, net	\$	4,338,720	\$	2,590,715

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. Property and equipment included organization costs of less than \$0.1 million related to cost incurred in the establishment of foreign subsidiaries. The recorded depreciation and amortization expense was \$877,205, \$525,008, and \$306,718 in the years ended December 31, 2012, 2011 and 2010, respectively.

### 5. Accrued Liabilities

Accrued liabilities consisted of the following:

December 31,				
	2012		2011	
\$	488,458	\$	975,589	
	313,597		*****	
	844,546		393,672	
	7,206,446		6,299,712	
	1,303,589		656,125	
	944,892		3,886,180	
	3,117,973		735,256	
	_		3,220,421	
	<del>-</del> .		1,089,531	
	4,945,861		4,191,058	
\$	19,165,362	\$	21,447,544	
	\$	\$ 488,458 313,597 844,546 7,206,446 1,303,589 944,892 3,117,973 — 4,945,861	\$ 488,458 \$ 313,597 844,546 7,206,446 1,303,589 944,892 3,117,973 4,945,861	

December 31

### 6. Third-party Agreements

AstraZeneca UK Limited ("AstraZeneca")

In November 2012, the Company entered an exclusive distribution and license agreement with AstraZeneca to commercialize fidaxomicin tablets for the treatment of Clostridium-difficile infection in Latin America, including Brazil, Central America, Mexico and the Caribbean. Under the terms of the license agreement, the Company will provide to AstraZeneca the completed preclinical and clinical data, regulatory information and documents, testing information, protocols and any know-how relating to fidaxomicin. In addition to the transfer of know-how, the Company will provide drug product for purposes of conducting validation testing in connection with seeking regulatory approval in the covered territories for commercial use of the product. AstraZeneca will be performing, at its own expense, the work required to obtain regulatory approval and commercialization in the covered territories. Under the terms of the agreement, the Company received a \$1.0 million up-front payment.

The Company is eligible to receive up to \$3.0 million in aggregate contingent payments on the first commercial sale in certain countries, and up to \$19.0 million on the achievement of sales-related targets for fidaxomicin in the specified regions. In addition, under the terms of a supply agreement entered into between the Company and AstraZeneca on the same date, the Company also is entitled to receive payments that provide a return resulting in a double-digit percent of net sales in the territory.

The Company assessed the deliverables under the authoritative guidance for multiple element arrangements. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset or another performance obligation. Once the Company identified the deliverables under the arrangement, the Company determined whether or not the deliverables can be accounted for as separate units of accounting and determined the appropriate method of revenue recognition for each element. The Company identified the two units of accounting as the license and the related know-how and the supply of drug product for validation testing. As of December 31, 2012, the Company recognized \$0.7 million of the \$1.0 million up-front payment, as the Company determined that revenue was earned upon the delivery of license rights and related know-how. The remaining \$0.3 million will be recognized upon delivery of the batches manufactured for validation testing, which is anticipated to be complete during the three months ending March 31, 2013. The Company has determined that the achievement of the performance conditions associated with the contingent payments is solely based on the performance of AstraZeneca and that the payments do not meet the criteria for a milestone under the revised authoritative guidance for contingent milestones. The Company will recognize the revenue for the contingent payments when the performance condition is achieved.

Specialised Therapeutics Australia Pty. Ltd. ("STA")

In June 2012, the Company entered into a distribution and license agreement with STA to register and commercialize fidaxomicin in Australia and New Zealand for the treatment of CDI. Under the distribution and license agreement, STA is responsible for all costs associated with the registration and commercialization of fidaxomicin in Australia and New Zealand. In addition, the Company entered a supply agreement with STA to supply product for the registration and commercial activities of STA and its sublicensees. Upon signing the distribution and license agreement, STA made a payment of \$0.5 million related to expenses incurred by the Company in connection with pre-approved activities in Australia which was recognized as contract revenue in 2012.

The Company is entitled to receive contingent payments, which may exceed \$1.5 million, upon the achievement of cumulative net sales targets and also will receive payments for the supply of fidaxomic to STA. The Company has determined that the achievement of the performance conditions associated with the contingent payments is solely based on the performance of STA and that the payments do not meet the criteria for a milestone under the revised authoritative guidance for contingent milestones. The Company will recognize the revenue for the contingent payments when the performance condition is achieved.

Astellas Pharma Inc. ("Astellas Japan")

In March 2012, the Company entered into a collaboration and license agreement with Astellas Japan pursuant to which the Company granted to Astellas Japan an exclusive, royalty-bearing license under certain of its know-how and intellectual property to develop and commercialize fidaxomicin in Japan. Under the terms of the collaboration and license agreement, and at its expense, Astellas Japan agreed to use commercially reasonable efforts to develop and commercialize fidaxomicin in Japan and achieve certain additional regulatory and commercial diligence milestones with respect to fidaxomicin in Japan. In addition, under the terms of the collaboration and license agreement, Astellas Japan granted to the Company an exclusive, royalty-free license under know-how and intellectual property generated by Astellas Japan and its sublicensees in the course of developing fidaxomicin and controlled by Astellas Japan or its affiliates for use by the Company and any of its sublicensees in the development and commercialization of fidaxomicin outside Japan and, following termination of the collaboration and license agreement and subject to payment by the Company of a single-digit royalties, in Japan. In addition, under the terms of a supply agreement entered into by Astellas Japan and Optimer Europe, on the same date as the collaboration and license agreement, Optimer Europe will be the exclusive supplier of fidaxomicin to Astellas Japan for Astellas Japan's development and commercialization activities in Japan during the term of the supply agreement.

Under the terms of the collaboration and license agreement, Astellas Japan paid the Company an up-front fee equal to \$20.0 million in April 2012. The Company also is eligible to receive additional contingent cash payments totaling up to \$70.0 million upon the achievement by Astellas Japan of specified regulatory and commercial milestones. In addition, the Company will be entitled to receive high-single-digit royalties on net sales of fidaxomicin products in Japan above an agreed threshold, which royalties are subject to reduction in certain limited circumstances. Such royalties will be payable by Astellas Japan on a product-by-product basis until a generic product accounts for a specified market share of the applicable fidaxomicin product in Japan. Under the supply agreement, in exchange for commercial supply of fidaxomicin, Astellas Japan is obligated to pay Optimer Europe a price equal to net sales of fidaxomicin products in Japan minus a discount that is based on a high-double-digit percentage of such net sales and a mark-up to cost of goods. This price will be payable by Astellas Japan on a product-by-product basis for commercial supply until a generic product accounts for a specified market share of the applicable fidaxomicin product in Japan.

The collaboration and license agreement will continue in effect on a product-by-product basis until expiration of Astellas Japan's obligation to pay royalties with respect to each fidaxomicin product in Japan, unless terminated early by either party. Following expiration of the collaboration and license agreement, Astellas Japan's license to develop and commercialize the applicable fidaxomicin product will become non-exclusive. Each of the Company and Astellas Japan may terminate the collaboration and license agreement prior to expiration upon the material breach of such agreement by the other party or upon the bankruptcy or insolvency of the other party. In addition, the Company may terminate the collaboration and license agreement prior to expiration in the event Astellas Japan or any of its affiliates or sublicensees commences an interference or opposition proceeding with respect to, challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to, any patent licensed to it under the collaboration and license agreement. Astellas Japan may terminate the collaboration and license agreement prior to expiration for any reason upon 180 days' prior written notice to the Company. Upon any such termination, the license granted to Astellas Japan (in total or with respect to the terminated product, as applicable) will terminate and revert to the Company. The supply agreement will continue in effect until terminated by either party. Each of Optimer Europe and Astellas Japan may terminate the supply agreement (i) upon the material breach of such agreement by the other party, (ii) upon the bankruptcy or insolvency of the other party or (iii) on a product-by-product basis following expiration of Astellas Japan's obligation to pay the price described above with respect to the applicable fidaxomicin product, or in its entirety following expiration of Astellas Japan's obligation to pay the price described above with respect to all fidaxomicin products.

The Company assessed the deliverables under the authoritative guidance for multiple element arrangements. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset or another performance obligation. Once the Company identified the deliverables under the arrangement, the Company determined whether or not the deliverables can be accounted for as separate units of accounting, and the appropriate method of revenue recognition for each element. During the year ended December 31, 2012, the Company recognized \$19.9 million of the \$20.0 million up-front payment, as the Company determined that revenue was earned upon the delivery of license rights and related know-how. The remaining \$0.1 million will be amortized over the term of the agreement and relates to the Company's future obligation to Astellas Japan to provide support in regulatory inquires and additional data as they are generated through the Company's U.S. operations.

# Cubist Pharmaceuticals, Inc.("Cubist")

In April 2011, the Company entered into a co-promotion agreement with Cubist pursuant to which the Company engaged Cubist as its exclusive partner for the promotion of DIFICID in the United States. Under the terms of the agreement, the Company and Cubist have agreed to co-promote DIFICID to physicians, hospitals, long-term care facilities and other healthcare institutions as well as jointly to provide medical affairs support for DIFICID. In conducting their respective co-promotion activities, each party is obligated under the agreement to commit minimum levels of personnel, and Cubist is obligated to tie a portion of the incentive compensation paid to its sales representatives to the promotion of DIFICID in the United States. Under the terms of the agreement, the Company is responsible for the distribution of DIFICID in the United States and for recording revenue from sales of DIFICID and agreed to use commercially reasonable efforts to maintain adequate inventory and third-party logistics support for the supply of DIFICID in the United States. In addition, Cubist agreed to not promote competing products in the United States during the term of the agreement and, subject to certain exceptions, for a specified period of time thereafter. The initial term of the agreement is two years from the date of first commercial sale of DIFICID in the United States, subject to renewal or early termination as described below. We currently do not anticipate renewing the co-promotion agreement when it expires on July 31, 2013, and will evaluate expanding our field force to detail the hospitals currently covered only by a Cubist representative.

In exchange for Cubist's co-promotion activities and personnel commitments, the Company is obligated to pay a quarterly fee of approximately \$3.8 million to Cubist (\$15.0 million per year), beginning upon the commencement of the sales program of DIFICID in the United States. Except for the first quarterly payment which the Company paid in advance, all payments are paid in arrears. Cubist also is eligible to receive an additional \$5.0 million in the first year after first commercial sale and \$12.5 million in the second year after first commercial sale if mutually agreed upon annual sales targets are achieved, as well as a portion of the Company's gross profits derived from net sales above the specified annual targets, if any. During 2012, the Company achieved the first year sales target and expensed \$23.2 million, which consisted of \$14.7 million in quarterly co-promotion fees, \$5.0 million for the year-one sales target bonus and \$3.5 million for Cubist's portion of the gross profit on net sales above the year-one target.

The agreement may be renewed by mutual agreement of the parties for additional, consecutive one-year terms. Cubist and the Company each may terminate the agreement prior to expiration upon the uncured material breach of the agreement by the other party or upon the bankruptcy or insolvency of the other party. In addition, the Company may terminate the agreement, subject to certain limitations, if (i) the Company withdraws DIFICID from the market in the United States, (ii) Cubist fails to comply with applicable laws in performing its obligations, (iii) Cubist undergoes a change of control, (iv) certain market events occur related to Cubist's product CUBICIN® (daptomycin for injection) in the United States or (v) Cubist undertakes certain restructuring activities with respect to its sales force. Cubist may terminate the agreement, subject to certain limitations, if (i) the Company experiences certain supply failures in relation to the demand for DIFICID in the United States, (ii) the Company is acquired by certain types of entities, including competitors of Cubist, (iii) certain market events occur related to CUBICIN in the United States or (iv) the Company fails to comply with applicable laws in performing its obligations.

# Astellas Pharma Europe Ltd.("APEL")

In February 2011, the Company entered into a collaboration and license agreement with APEL pursuant to which the Company granted to APEL an exclusive, royalty-bearing license under certain of the Company's know-how and intellectual property to develop and commercialize fidaxomicin in Europe and certain other countries in the Middle East, Africa and the Commonwealth of Independent States, or CIS. In March 2011, the parties amended the collaboration and license agreement and the supply agreement (described below) to include certain additional countries in the CIS and all additional territories in Africa (all such countries and territories are referred to as the APEL territories). Under the terms of the collaboration and license agreement, APEL has agreed to use commercially reasonable efforts to develop and commercialize fidaxomicin in the APEL territories at its expense, and to achieve certain additional regulatory and commercial diligence milestones with respect to fidaxomicin in the APEL territories. The Company and APEL also may agree to collaborate in, and share data resulting from, global development activities with respect to fidaxomicin, in which case the Company and APEL will be obligated to co-fund such activities. In addition, under the terms of the collaboration and license agreement, APEL granted the Company an exclusive, royalty-free license under know-how and intellectual property generated by APEL and its sublicensees in the course of developing fidaxomicin and controlled by APEL or its affiliates for use by the Company and any of its sublicensees in the development and commercialization of fidaxomicin outside the APEL territories and, following termination of the agreement and subject to payment by the Company of single-digit royalties, in the APEL territories. In addition, under the terms of a supply agreement entered into between the Company and APEL on the same date, the Company will be the exclusive supplier of fidaxomicin to APEL for APEL's development and commercialization activities in the APEL territories during the term of the supply agreement, and APEL is obligated to pay the Company an amount equal to cost plus an agreed mark-up for such supply.

Under the terms of the collaboration and license agreement, APEL paid the Company an up-front fee of \$69.2 million in March 2011, and the Company recognized a milestone payment of 40.0 million Euros in December 2011 as the result of APEL

attaining EMA approval of DIFICLIR. APEL paid the Company 50.0 million Euros in June 2012, which consisted of the 40.0 million Euro approval milestone payment and a 10.0 million Euro milestone payment for the first commercial launch of DIFICLIR in an APEL territory. The Company is eligible to receive additional contingent cash payments totaling up to 65.0 million Euros, upon the achievement by APEL of additional specified commercial milestones.

In addition, the Company is entitled to receive escalating double-digit royalties ranging from the high teens to low twenties on net sales of DIFICLIR products in the APEL territories, which royalties are subject to reduction in certain, limited circumstances. Such royalties are payable by APEL on a product-by-product and country-by-country basis until a generic product accounts for a specified market share of the applicable DIFICLIR product in the applicable country. APEL launched DIFICLIR in Europe during the second quarter of 2012.

The Company assessed the deliverables under the authoritative guidance for multiple element arrangements. Based on the Company's analysis, it determined that all of the up-front payment was earned upon the delivery of the license and related know-how, which occurred by March 31, 2011.

The agreements with APEL will continue in effect on a product-by-product and country-by-country basis until expiration of APEL's obligation to pay royalties with respect to each fidaxomicin product in each country in the APEL territory, unless terminated early by either party as more fully described below. Following expiration, APEL's license to develop and commercialize the applicable fidaxomicin product in the applicable country will become non-exclusive. The Company and APEL each may terminate either of the agreements, prior to expiration, upon the material breach of such agreement by the other party or upon the bankruptcy or insolvency of the other party. In addition, the Company may terminate the agreements prior to expiration in the event APEL or any of its affiliates or sublicensees commences an interference or opposition proceeding with respect to, challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to any patent licensed to it. APEL may terminate the agreements prior to expiration for any reason on a product-by-product and country-by-country basis upon 180 days' prior written notice to the Company. Upon any such termination, the license granted to APEL (in total or with respect to the terminated product or terminated country, as applicable) will terminate and revert to the Company.

### Par Pharmaceuticals, Inc.

In February 2007, the Company repurchased the rights to develop and commercialize fidaxomicin in North America and Israel from Par under a prospective buy-back agreement. The Company paid Par a \$5.0 million milestone payment in June 2010 for the successful completion by the Company of its second pivotal Phase 3 trial for fidaxomicin. The Company is obligated to pay Par a 5% royalty on net sales by the Company, its affiliates or its licensees of fidaxomicin in North America and Israel, including Cubist, and a 1.5% royalty on net sales by the Company or its affiliates of fidaxomicin in the rest of the world. In addition, the Company is required to pay Par a 6.25% royalty on net revenues it receives related to fidaxomicin in connection with licensing of its right to market fidaxomicin in the rest of the world, such as the licenses the Company has granted to its partners in territories outside the United States and Canada. The Company is obligated to pay each of these royalties, on a country-by-country basis for seven years commencing on the applicable commercial launch in each such country. For the years ended December 31, 2012 and 2011, the Company expensed an aggregate of \$5.0 million and \$8.7 million, respectively, in royalties to Par.

# Biocon Limited ("Biocon")

In May 2010, the Company entered into a long-term supply agreement with Biocon for the commercial manufacture of fidaxomicin active pharmaceutical ingredient ("API"). Pursuant to the agreement, Biocon agreed to manufacture and supply the Company, up to certain limits, fidaxomicin API and, subject to certain conditions, the Company agreed to purchase from Biocon at least a portion of its requirements for fidaxomicin API in the United States and Canada. The Company previously paid to Biocon \$2.5 million for certain equipment purchases and manufacturing scale-up activities, and is entitled to recover up to \$1.5 million of this amount under the supply agreement in the form of discounted prices for fidaxomicin API. As of December 31, 2012, the Company had recovered approximately \$0.9 million of the \$1.5 million. Unless both Biocon and the Company agree to extend the term of the supply agreement, it will terminate seven and one-half years from the date the Company obtained marketing authorization for DIFICID in the United States. The supply agreement may be earlier terminated (i) by either party by giving two and one-half years notice after the fifth anniversary of the Effective Date or upon a material breach of the supply agreement by the other party, (ii) by the Company upon the occurrence of certain events, including Biocon's failure to supply requested amounts of fidaxomicin API, or (iii) by Biocon upon the occurrence of certain events, including the Company's failure to purchase amounts of fidaxomicin API that it indicates in binding forecasts.

### Patheon Inc. ("Patheon")

In June 2011, the Company entered into a commercial manufacturing services agreement with Patheon to manufacture and supply fidaxomicin drug products, including DIFICID, in North America, Europe and other countries, subject to agreement by the parties to any additional fees for such countries. The Company agreed to purchase a specified percentage of its fidaxomicin product requirements for North America and Europe from Patheon or its affiliates.

The term of the agreement extends through December 31, 2016 and automatically will renew for subsequent two year terms unless either party provides a timely notice of its intent not to renew or unless the Agreement is terminated early pursuant to its terms. Patheon and the Company may terminate the agreement prior to expiration upon the uncured material breach of the agreement by the other party or upon the bankruptcy or insolvency of the other party. In addition, the agreement will terminate with respect to any fidaxomicin product if the Company provides notice to Patheon that it no longer requires manufacturing services for such product because the product has been discontinued. Additionally, the Company may terminate the agreement, subject to certain limitations, (i) with respect to any fidaxomicin product if any regulatory authority takes any action or raises any objection that prevents the Company from importing, exporting, purchasing or selling such product, or if the Company determine to discontinue development or commercialization of such product for safety or efficacy reasons, (ii) if any regulatory authority takes an enforcement action against Patheon's manufacturing site that relates to fidaxomicin products or that could reasonably be expected to adversely affect Patheon's ability to supply fidaxomicin products to us, (iii) if Patheon is unable to deliver or supply any firm orders for any two calendar quarters during any four consecutive calendar quarters, (iv) if Patheon uses any debarred or suspended person in the performance of its service obligations under the agreement or (v) if Patheon fails to meet certain production yield requirements in relation to fidaxomicin API.

# Cempra, Inc. ("Cempra")

In March 2006, the Company entered into a collaborative research and development and license agreement with Cempra. The Company granted to Cempra an exclusive worldwide license, except in the Association of Southeast Asian Nations, or ASEAN, 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 equity of Cempra representing an ownership of less than 20%. The Company may 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 milestone payments will be triggered upon the completion of certain clinical development milestones and, in certain instances, regulatory approval of products. The Company also may receive royalty payments based on a percentage of net sales of licensed products.

Pursuant to the agreement, Cempra granted the Company an exclusive license whereby Cempra may 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.

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 also may 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 will survive upon the express election of the non-terminating party.

The Company has assessed milestones under the revised authoritative guidance for research and development milestones and determined that the preclinical milestone payments, as defined in the agreement, meet the definition of a milestone as they are (i) events that can only be achieved in part on the Company's past performance or upon the occurrence of a specific outcome resulting from the Company's performance, (ii) there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) they result in additional payments being due to the Company. Clinical development and commercial milestone payments, however, currently do not meet these criteria as their achievement is solely based on the performance of Cempra.

In February 2012, Cempra completed an initial public offering at which time the Company's equity interest in Cempra was converted to 125,646 shares of common stock. The Company considers its equity interest in Cempra as available-for-sale (see Note 2).

In June 2012, Cempra completed its first Phase 2 clinical trial of solithromycin (CEM101) in patients with community-acquired bacterial pneumonia, which triggered a \$1.0 million milestone payment to the Company. To date, the Company has received \$1.5 million in payments from this collaboration.

# Optimer Biotechnology, Inc.

In October 2009, the Company entered into certain transactions involving OBI, its then wholly-owned subsidiary, to provide funding for the development of two of its early-stage, non-core programs. The transactions with OBI included an intellectual property assignment and license agreement, pursuant to which the Company assigned to OBI certain patent rights, information and know-how related to OPT-88 and OPT-822/821. In anticipation of these transactions, the Company assigned, and OBI assumed, its rights and obligations under related license agreements with Memorial Sloan-Kettering Cancer Center. Under the intellectual property assignment and license agreement, the Company is eligible to receive up to \$10 million in milestone payments related to the development of OPT-822/821 and is eligible to receive royalties on net sales of any product which is commercialized under the program. The term of the intellectual property assignment and license agreement continues until the last to expire of certain patents assigned to and licensed by the Company to OBI.

In January 2012, OBI and the Company executed a letter of agreement which provided the Company the right of first refusal if OBI or one of its affiliates receives any offer to obtain an exclusive, royalty-bearing license (including the right to sublicense) under the OPT-822/821 patents and the OBI OPT-822/821 technology to develop, make, have made, use, sell, offer for sale, have sold and import OPT-822/821 products in the United States, Europe or other specified territories. In the letter of agreement, as consideration for the grant of the right of first refusal, the Company waived certain of OBI's obligations under the intellectual property assignment and license agreement. The letter of agreement expires 10 years from the effective date of the agreement.

In the fourth quarter of 2012, the Company sold its remaining equity interest in OBI (see Note 9) but retains its rights to receive milestone and royalty payments related to OPT-822/821 under the Intellectual Property Assignment and License Agreement. The Company retains a right of first refusal to license commercial rights to OPT-822/821 in the United States, Europe or other specified territories.

Scripps Research Institute ("TSRI")

In July 1999, the Company acquired exclusive, worldwide rights certain drug technology from TSRI. The agreement with TSRI includes the license to the Company of patents, patent applications and copyrights related to the 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 and carbohydrate mimetics.

Under the four agreements with TSRI, the Company paid TSRI license fees consisting of an aggregate of 239,996 shares of the Company's common stock with a deemed aggregate fair market value of \$46,400, as determined on the dates of each such payment. In October 2009, the Company assigned to OBI one of the agreements with TSRI related to OPT-88 which, after further evaluation, OBI decided not to pursue. In February 2011, OBI and TSRI agreed to terminate the agreement and OBI returned the patents related to OPT-88. Under each of the three remaining agreements, the Company owes TSRI royalties based on net sales by the Company, the Company's 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 three remaining agreements, the Company also will owe TSRI payments upon achievement of certain milestones. In two of the three TSRI agreements, the milestones are the successful completion of a Phase 2 trial or its foreign equivalent, the submission 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 submission 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 the three remaining TSRI agreements, is approximately \$11.1 million. The Company is currently not developing any products covered by the TSRI agreements.

# 7. Commitments and Contingencies

### Leases

The Company's facilities consist of approximately 45,000 square feet of laboratory and office space in San Diego, California, and 24,000 square feet of office space in Jersey City, New Jersey. The lease for the San Diego facility expires in August 2022 subject to two, five-year renewal options. The lease for the facility in Jersey City expires in July 2018, subject to one, five-year renewal option.

The Company recorded deferred rent of \$938,520 and \$151,141 at December 31, 2012 and 2011, respectively, in conjunction with these lease agreements.

At December 31, 2012, annual minimum rental payments due under the Company's operating leases are as follows:

Years Ending December 31,	
2013	\$ 2,333,050
2014	2,558,345
2015	2,628,166
2016	2,684,290
2017 and thereafter	12,140,751
Total minimum lease payments	\$ 22,344,602

Rent expense was \$3.5 million, \$1.6 million and \$1.1 million, for the years ended December 31, 2012, 2011, and 2010, respectively.

# Other Commitments

The Company had firm purchase order commitments for the acquisition of inventory from Biocon and Patheon as of December 31, 2012 and 2011 of \$16.3 million and \$1.0 million, respectively.

Pursuant to our co-promotion with Cubist, the Company is obligated to pay a quarterly fee of \$3.8 million (\$15.0 million per year) beginning in July 2011, the commencement of the commercial launch of DIFICID in the United States. At December 31, 2012, \$7.5 million of the fee remained to be paid.

# Contingencies

In March 2012, the Company became aware of an attempted grant in September 2011 to Dr. Michael Chang of 1.5 million technical shares of OBI. The Company engaged external counsel to assist it in an internal review and determined that the attempted grant may have violated certain applicable laws, including the Foreign Corrupt Practices Act (the "FCPA").

In April 2012, the Company self-reported the results of its preliminary findings to the U.S. Securities and Exchange Commission (the "SEC") and the U.S. Department of Justice (the "DOJ"), which included information about the attempted grant and certain related matters, including a potentially improper \$300,000 payment in July 2011 to a research laboratory involving an individual associated with the OBI share grant. At that time, the Company terminated the employment of its then-Chief Financial Officer and its then-Vice President, Clinical Development. The Company also removed Dr. Michael Chang as the Chairman of its Board of Directors and requested that Dr. Michael Chang resign from the Board of Directors, which he has not. The Company continued its investigation and its cooperation with the SEC and the DOJ.

As a result of the continuing internal investigation, in February 2013, the independent members of the Board of Directors determined that additional remedial action should be taken in light of prior compliance, record keeping and conflict-of-interest issues surrounding the potentially improper payment to the research laboratory and certain related matters. On February 26, 2013, the Company's then-President and Chief Executive Officer and its then-General Counsel and Chief Compliance Officer resigned at the request of the independent members of the Board of Directors.

In addition, over the past year, the Company has revised its compliance policies, strengthened its approval procedures and implemented training and internal audit procedures to make compliance and monitoring more comprehensive.

The Company continues to cooperate with the SEC and DOJ, including by responding to informal document and interview requests, conducting in-person meetings and updating these authorities on its findings with respect to the attempted OBI technical share grant, the potentially improper payment to the research laboratory and certain matters that may be related. The Company is unable to predict the ultimate resolution of these matters, whether it will be charged with violations of applicable civil or criminal laws or whether the scope of the investigations will be extended to new issues. The Company also is unable to predict what potential penalties or other remedies, if any, the authorities may seek against it or any of its current or former employees, or what the collateral consequences may be of any such government actions.

### 8. Stockholders' Equity

Public Offerings

In March 2009, the Company received approximately \$32.7 million in net proceeds from the sale of its securities in a registered direct offering to institutional investors. The Company sold 3,252,366 million shares and warrants to purchase up to an aggregate of 91,533 shares of its common stock. The warrants were exercisable at an exercise price of \$10.93 per share and were exercised in June 2011.

In March 2010, the Company completed the sale of 4,887,500 shares of its common stock in a public offering which included 637,500 shares sold pursuant to the full exercise of an overallotment option previously granted to the underwriter. The net proceeds to the Company from the sale of shares in the offering were approximately \$51.2 million.

In July 2010 and in April 2012, the Company issued 585,762 shares and 286,260 shares, respectively, of common stock to AFOS, LLC, valued at \$5.2 million and \$3.8 million, respectively, as consideration for the engagement of an affiliate of AFOS to provide research and development, sales, marketing and business development consulting services to the Company.

In February 2011, the Company completed the sale of 6,900,000 shares of its common stock in a public offering which included 900,000 shares sold pursuant to the full exercise of an overallotment option previously granted to the underwriter. The net proceeds to the Company from the sale of shares in the offering were approximately \$73.1 million.

Equity Compensation Plans

Optimer Pharmaceuticals, Inc.

Stock Options

In November 1998, the Company adopted the 1998 Stock Plan (the "1998 Plan"). The Company terminated and ceased granting options under the 1998 Plan upon the closing of the Company's initial public offering in February 2007.

In December 2006, the Company's board of directors approved the 2006 Equity Incentive Plan ("2006 Plan") which became effective upon the closing of the Company's initial public offering. The 2006 Plan was succeeded by the 2012 Equity Plan ("2012 Plan") which became effective upon approval by the Company's stockholders on May 9, 2012. After May 9, 2012, no additional stock awards will be awarded under the 2006 Plan. However, all outstanding stock awards granted under the 2006 Plan remain subject to the terms of the 2006 Plan.

The 2012 Plan is a continuation of the 2006 Plan. Upon its adoption, the maximum number of shares of the Company's common stock issuable under the 2012 Plan was 11,289,455, which consisted of (a) 3,400,000 new shares and (b) the number of unallocated shares remaining available for grant of new awards under the 2006 Plan as of May 9, 2012, which include shares subject to outstanding stock awards granted under the 2006 Plan that (i) expire or terminate for any reason prior to exercise or settlement, (ii) are forfeited because of the failure to meet a contingency or condition required to vest such shares or repurchased at the original issuance price or (iii) are re-acquired or withheld (or not issued) to satisfy a tax withholding obligation in connection with an award other than a stock option or stock appreciation right.

Options granted under the 1998 Plan, the 2006 Plan and the 2012 Plan generally expire 10 years from the date of grant (five years for a 10% or greater stockholder) and vest over a period of four years. 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.

Restricted Stock Units

From time to time the Company grants restricted stock units ("RSUs") to its executives, board members and employees. RSUs are valued based on the fair market value of the Company's stock on the date of grant.

Performance-based Stock Options and Performance-based Restricted Stock Units

In February 2012, the Compensation Committee granted to certain executives performance-based RSUs covering up to an aggregate of 250,000 shares of common stock, which vest over time beginning on the date the Company determines that a specified product revenue goal has been achieved. At December 31, 2012, the management had determined that the specified product revenue goal was not achieved. As a result, these RSUs were cancelled.

On May 2010, the Company's Board of Directors appointed Pedro Lichtinger as its President and CEO and as a member of its Board of Directors. Pursuant to Mr. Lichtinger's offer letter, he received performance-based stock options to purchase up to an aggregate of 480,000 shares of common stock and performance-based RSUs covering up to an aggregate of 120,000 shares of common stock, which vest over time beginning on the dates the Company achieves specified development and commercialization goals. In February 2011, one of the performance criteria was met, and, in May 2011, another one of the performance criteria was met. As a result, 1/4th of the performance-based stock options and performance-based restricted stock units related to each goal vested in February 2012 and May 2012, respectively, and the remaining shares related to each goal will vest in 36 equal monthly installments thereafter.

Simultaneously with Mr. Lichtinger's appointment, Michael Chang resigned as the Company's President and CEO. The Company entered into a consulting agreement with Dr. Michael Chang to provide general consulting services. Pursuant to his consulting agreement and as part of his compensation, Dr. Michael Chang received performance-based stock options to purchase up to an aggregate of 400,000 shares of common stock which vest over time beginning on the dates certain regulatory filings are accepted and approved. Dr. Michael Chang's consulting agreement was terminated in April 2012 and, as a result, the unvested portion of the performance-based options was cancelled. Prior to the termination of his consulting agreement, 248,437 options vested. However, due to Dr. Michael Chang's continuing role as a director, his other equity awards remain outstanding and continue to vest as per the vesting term of the awards.

The performance-based stock options, performance-based restricted stock units and stock grant were made under the 2006 Plan.

Weighted

Following is a summary of stock option activity, including performance-based stock options:

	Options	Average Price
Options outstanding as of December 31, 2009	2,466,751	\$ 5.69
Granted	1,815,450	\$ 11.88
Exercised	(552,253)	\$ 2.12
Canceled/forfeited/expired	(140,322)	\$ 11.39
Options outstanding as of December 31, 2010	3,589,626	\$ 9.15
Options outstanding as of December 31, 2010	3,427,500	\$ 12.26
Exercised	(347,803)	\$ 5.35
Canceled/forfeited/expired  Options outstanding as of December 31, 2011	(486,823)	\$ 10.87
Options outstanding as of December 31, 2011	6,182,500	\$ 10.95
Granted	1,495,330	\$ 13.70
Exercised	(616,519)	\$ 8.19
Canceled/forfeited/expired	(766,737)	\$ 12.36
Options outstanding as of December 31, 2012	6,294,574	\$ 11.70

# Stock Option Valuation

Stock options are valued using the Black-Scholes option pricing model on the date of grant. This option pricing model involves a number of estimates, including the expected lives of stock options, the Company's anticipated stock volatility and applicable interest rates. The Company recognizes compensation expense for performance-based stock awards granted to employees under the accelerated attribution method. The following table shows the assumptions used to compute stock-based compensation expense for the stock options and restricted stock units during the years ended December 31, 2012, 2011 and 2010, using the Black-Scholes option pricing model:

Stock Options Including Performance-based Stock Options	2012	2011	2010
Risk-free interest rate	0.67-1.516%	1.84-3.46%	2.27-3.53%
Dividend yield	0.00%	0.00%	0.00%
Expected life of options (years)	5.02-6.08	5.27-9.49	5.02-10.00
Volatility	69.71-75.30%	69.13-73.63%	69.30-79.07%

The risk-free interest rate assumption was based on the 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 for the foreseeable future. The weighted-average expected life of options was calculated using the simplified

method. Due to the Company's limited history as a commercial entity, the Company used the historical volatility of comparable companies whose share prices are publicly available.

The aggregate intrinsic value of options exercised during the year ended December 31, 2012, 2011 and 2010 was \$4.2 million, \$2.5 million and \$4.7 million, respectively. The aggregate intrinsic value of options outstanding and options exercisable as of December 31, 2012 was \$2.5 million and \$2.5 million, respectively.

The following table summarizes information concerning outstanding and exercisable stock options as of December 31, 2012:

			Decem	ber 31, 2012			
		Options Outstanding	Options Ex	ercisabl	e		
Exercise Price	Number of Shares Subject to Options Outstanding	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price		Number of Shares Exercisable	A	/eighted Average rcise Price
\$1.08 - \$11.41	1,802,672	5.91	\$	8.66	1,373,862	\$	8.03
\$11.42 - \$12.34	2,068,173	6.31	\$	12.05	1,093,420	\$	12.01
\$12.42 - \$13.84	1,659,188	7.64	\$	13.23	292,544	\$	12.94
\$13.90 - \$15.46	764,541	8.69	\$	14.63	186,113	\$	14.46
\$1.08 - \$15.46	6,294,574	6.83	\$	11.70	2,945,939	\$	10.40

Of the options outstanding, options to purchase 2,945,939 shares were vested as of December 31, 2012, with a weighted average remaining contractual life of 5.46 years and a weighted average exercise price of \$10.40 per share, while options to purchase 3,348,635 shares were unvested.

Based on these assumptions, the weighted average grant-date fair values of stock options granted during the years ended December 31, 2012, 2011 and 2010 were \$13.70, \$7.75 and \$7.35 per share, respectively.

As of December 31, 2012, the total unrecognized compensation expense related to stock options was \$22.5 million and the related weighted-average period over which it is expected to be recognized is 2.87 years.

During the year ended December 31, 2010, the Company granted the then-Chairman of Board, 65,000 fully-vested shares of common stock.

Following is a summary of RSUs activity, including performance-based RSUs:

	RSUs	eighted- age Price
RSUs outstanding as of December 31, 2009	<u> </u>	\$ 
Granted	120,000	\$ 12.34
Vested		\$ 
Canceled/forfeited		\$ 
RSUs outstanding as of December 31, 2010	120,000	\$ 12.34
Granted	21,000	\$ 11.89
Vested		\$ 
Canceled/forfeited		\$ 
RSUs outstanding as of December 31, 2011	141,000	\$ 12.27
Granted	547,040	\$ 13.54
Vested	(24,957)	\$ 13.94
Canceled/forfeited	(290,800)	\$ 13.60
RSUs outstanding as of December 31, 2012	372,283	\$ 13.13

Employee Stock Purchase Plan

Concurrent with the Company's initial public offering in February 2007, the Company's board of directors adopted the employee stock purchase plan ("ESPP") 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. Pursuant to this provision, 300,000 additional shares of the Company's common stock were reserved for issuance under the ESPP on January 1, 2008. The Company's board of directors determined to reserve 300,000 shares as of January 1, 2012 and zero additional shares under the ESPP as of January 1, 2011 and 2010.

As of December 31, 2012, there were 173,844 shares of common stock issued and 390,194 shares remained available for issuance under the ESPP.

The following table shows the assumptions used to compute stock-based compensation expense for the stock purchased under the ESPP during the year ended December 31, 2012, 2011 and 2010 using the Black-Scholes option pricing model:

Employee Stock	2012 2011		2010
Risk-free interest rate	0.09%-0.15%	0.06%-0.18%	0.17-0.20%
Dividend yield	0.00%	0.00%	0.00%
Expected life (years)	0.5	0.5	0.5
Volatility	37.16%-43.56%	40.01%-73.53%	34.08-40.82%

For the years ended December 31, 2012, 2011 and 2010, the Company recorded stock-based compensation expense related to the ESPP of \$452,588, \$320,485 and \$119,281, respectively.

Total stock-based compensation expense, related to all of Optimer's stock options, restricted stock units and stock awards issued to employees and consultants and employee stock purchases, recognized for the years ended December 31, 2012, 2011 and 2010 was comprised as follows:

•	2012			2011	 2010
Research and development	\$	4,011,962	\$	3,176,997	\$ 1,596,515
Selling, general and administrative		8,678,876		8,407,951	4,622,332
Total stock-based compensation expense	\$	12,690,838	\$	11,584,948	\$ 6,218,847

Optimer Biotechnology, Inc.

Stock Options

Until February 7, 2012, the Company consolidated OBI into its results of operations and recoded stock based compensation related to options granted by OBI. The following table summarizes the stock-based compensation expense for OBI included in each operating expense line item in Optimer's consolidated statements of operations for the years ended December 31, 2012, 2011 and 2010:

	2012		2011		2010	
Research and development	\$	8,465	\$	60,463	\$	43,450
Selling, general and administrative		9,181		140,963		113,387
Stock-based compensation expense	\$	17,646	\$	201,426	\$	156,837

### 9. Investment in OBI

In February 2012, OBI issued 36 million newly-issued shares of its common stock, resulting in gross proceeds of approximately 540 million New Taiwan dollars (approximately \$18.3 million based on then-current exchange rates). The Company did not participate in the February 2012 financing. In March 2012, the Company sold 1.5 million shares of its equity interest in OBI. These transactions reduced the Company's ownership interest in OBI from a majority interest to a 42.9% interest and triggered consideration regarding whether or not to continue consolidating OBI, as well as an evaluation to consider whether OBI was a variable interest entity ("VIE").

As a result of its evaluation, the Company determined that OBI was not a VIE and that Optimer no longer had voting control or other forms of control over the operations and decision making of OBI. As a result of this evaluation, the Company de-consolidated OBI as of February 7, 2012 and de-recognized the OBI assets, liabilities and non-controlling interest from its financial statements and no longer consolidated its results of operations. Management applied de-consolidation accounting guidance, which included analyzing Optimer's investment in OBI at February 7, 2012 to determine the fair value on the date of de-consolidation and the related gain or loss upon de-consolidation. Based on available evidence, management determined that the fair value of Optimer's investment in OBI at February 7, 2012 was \$29.7 million. This fair value was based primarily on OBI's financing transaction in February 2012 in which shares of common stock were sold at approximately \$0.51 per share (based on then-current exchange rates). As a significant portion

of the additional investment in OBI was made by outside investors in an arms-length transaction and the common shares have the same rights and preferences as the shares held by Optimer, management determined that this price per share approximated fair market value as of February 7, 2012. The gain attributed to the de-consolidation of OBI was \$23.8 million. During a portion of 2012, Optimer provided consulting, purchasing and other services to OBI and billed OBI in the amount of approximately \$89,000 for such services. As of December 31, 2012, the Company is no longer providing consulting, purchasing, or other services to OBI.

As of the date of de-consolidation, and prior to the sale of its equity interest in OBI, the Company accounted for its investment in OBI under the equity method. The investment was adjusted for Optimer's share in the equity in net loss and cash contributions and distributions for the appropriate periods. In addition, the Company recorded adjustments to reflect the amortization of basis differences attributable to the fair values in excess of net book values of identified tangible and intangible assets. Based on a preliminary valuation, the fair value in excess of book value was attributed to in-process research and development related to a License and Collaboration Agreement for fidaxomicin and an Intellectual Property Assignment and License Agreement related to OBI's OPT-822/821 program (see Note 6). For the period post de-consolidation, the Company's equity method investment in OBI had been reduced by \$1.8 million to reflect its share in OBI losses during that period. Any difference between the carrying amount of the investment on the Company's balance sheet and the underlying equity in net assets was evaluated for impairment at each reporting period.

In May 2012, the Company purchased, at cost, 924,000 shares in OBI from the Company's President and Chief Executive Officer for approximately \$0.5 million, resulting in an increase in the fair value of the Company's investment in OBI.

During the fourth quarter of 2012, the Company sold all of its equity interest in OBI for \$60.0 million in gross proceeds. The gain attributed to the sale of OBI stock was \$31.5 million.

### 10. Income Taxes

During the year ended December 31, 2012, the Company completed a Section 382/383 analysis regarding the limitation of net operating loss and research and development credit carryforwards and determined that the entire amount of federal and state NOL and credit carryovers is available for utilization, subject to an annual limitation. Any carryforwards that will expire, prior to utilization and as a result of future limitations, will be removed from deferred tax assets with a corresponding reduction in the valuation allowance.

At December 31, 2012, the Company had federal, state and foreign tax net operating loss carryforwards of approximately \$184.0 million, \$195.1 million and \$7.3 million, respectively. If not utilized, the net operating carryforwards will begin expiring in 2020 for federal purposes and in 2015 for state purposes. The foreign loss carryforwards will begin expiring in 2019. In addition, the Company has federal and California research tax credit carryforwards of approximately \$7.0 million and \$4.7 million, respectively. The federal research and development credits carryforwards will begin to expire in 2020 unless previously utilized. The California research and development credit carryforwards do not expire. Under Sections 382 and 383 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 can be utilized annually in the future to offset taxable income. Any such annual limitations may significantly reduce out utilization of the net operating losses and credits before they expire.

The Company has \$3.7 million of net operating loss carryforwards related to excess stock option deductions which will result in an increase to additional paid-in-capital and a decrease in income taxes payable when the tax loss carryforwards are utilized.

The components of the income (loss) before provision for income taxes are as follows:

	_	2012	2011	 2010
United States	\$	(29,720,000)	\$ 12,666,000	\$ (44,309,000)
Foreign	100	(6,872,000)	(4,795,000)	 (3,000,000)
	\$	(36,592,000)	\$ 7,871,000	\$ (47,309,000)

Intraperiod tax allocation rules require the Company to allocate its provision for income taxes between continuing operations and other categories of earnings, such as other comprehensive income. In periods in which the Company has a year-to-date pre-tax loss from continuing operations and pre-tax income in other categories of earnings, such as other comprehensive income, the Company must allocate the tax provision to the other categories of earnings. The Company then records a related tax benefit in continuing operations. During 2012, the Company recorded unrealized gains on our investments in available-for-sale securities in other comprehensive income net of taxes. As a result, the Company recorded a \$281,000 tax benefit in continuing operations and a \$281,000 tax expense in other comprehensive income for the year ended December 31, 2012.

The provision for income taxes from continuing operations consists of the following:

	 2012	 2011	 2010
Current:			
Federal	\$ 867,000	\$ 	\$ _
State	24,000	20,000	
Foreign	·	 	 
Subtotal	891,000	20,000	—
Deferred:	,		
Federal	(1,140,000)		
State	(32,000)	 	 
Subtotal	 (1,172,000)		
Total	\$ (281,000)	\$ 20,000	\$ _

Significant components of the Company's deferred tax assets as of December 31, 2012 and 2011 are listed below. A valuation allowance of \$101.9 million and \$88.5 million at December 31, 2012 and 2011, 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:

	 2012		2011
Deferred tax assets:			
Net operating loss carryforwards	\$ 74,575,000	\$	65,478,000
Tax credits	10,133,000		9,559,000
Capitalized license, net	4,161,000		4,728,000
Stock based compensation	9,441,000		6,441,000
Other, net	4,715,000		2,251,000
Total deferred tax assets	103,025,000		88,457,000
Valuation allowance for deferred tax assets	(101,853,000)		(88,457,000)
Net deferred tax assets.	 1,172,000		
Unrealized gain on investments	(281,000)		_
	\$ 891,000	\$	_

Income taxes computed by applying the U.S. Federal statutory rates to income from continuing operations before income taxes are reconciled to the provision for income taxes set forth in the statement of earnings as follows:

	2012		2011	 2010
Tax expense (benefit) at statutory federal rate	\$ (12,441,000)	\$	2,676,000	\$ (16,085,000)
State tax expense (benefit), net of federal	(650,000)		53,000	(2,758,000)
Sales and deconsolidation of OBI	(1,819,000)		_	
Foreign subsidiary transactions	462,000		161,000	77,000
Generation of research and development credits	(548,000)	•	(2,047,000)	(1,273,000)
Stock compensation expense	604,000		317,000	(14,000)
Meals and entertainment	639,000		223,000	
Non-deductible legal expenses	289,000			
Non-deductible R&D expenses claimed as credits	11,000		505,000	356,000
Change in state effective rate	516,000		1,068,000	
Other	(739,000)		(402,000)	92,000
Change in valuation allowance	13,395,000		(2,534,000)	19,605,000
	\$ (281,000)	\$	20,000	\$

Due to operating losses since inception, a valuation allowance has been recognized to offset net deferred tax assets as realization of such deferred tax assets in not more likely than not. During fiscal 2012 and 2011, the valuation allowance on deferred tax assets increased by \$13.4 million and decreased by \$2.5 million, respectively.

Under the accounting guidance related to uncertain tax positions, 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, the guidance provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

There were no unrecognized tax benefits as of the date the Company adopted this guidance. As a result of the implementation of the guidance, the Company did not recognize an increase in the liability for unrecognized tax benefits and did not have any unrecognized tax benefits included in the balance sheet that would, if recognized, affect the effective tax rate. The adoption of the guidance did not impact the Company's financial condition, results of operations or cash flows.

The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest or penalties on the Company's Consolidated Balance Sheets at December 31, 2012 or December 31, 2011, and has not recognized interest and/or penalties in the statement of comprehensive income (loss) for the year ended December 31, 2012.

The Company is subject to taxation in the United States and various state and foreign jurisdictions. The Company's tax years for 2000 and forward are subject to examination by the United States and California tax authorities due to the carry forward of unutilized net operating losses and R&D credits.

The following table summarizes the changes to unrecognized tax benefits for the years ended December 31, 2012 and 2011:

Unrecognized tax benefits at January 1, 2011	\$	
Increase (decrease) current year positions		_
Increase (decrease) prior year positions		
Unrecognized tax benefits at December 31, 2011		
Increase (decrease) current year positions		385,000
Increase (decrease) prior year positions		1,502,000
Unrecognized tax benefits at December 31, 2012	_	1,887,000

As of December 31, 2012, the Company had \$1,887,000 of unrecognized tax benefits that, if recognized and realized, would affect the effective tax rate. In the next twelve months, the Company does not expect a significant change in its unrecognized tax benefits.

The future utilization of the Company's research and development credit carry forwards and net operating loss carryforwards to offset future taxable income may be subject to an annual limitation as a result of ownership changes that may have occurred previously or may occur in the future. The Tax Reform Act of 1986 (the "Act") limits a company's ability to utilize certain tax credit carryforwards and net operating loss carryforwards in the event of a cumulative change in ownership in excess of 50% as defined in the Act.

The American Taxpayer Relief Act of 2012, which reinstated the United States Federal Research and Development Tax Credit retroactively from January 1, 2012 through December 31, 2013, was not enacted into law until the first quarter of 2013. Therefore, the expected tax benefit resulting from such reinstatement for 2012 will not be reflected in the Company's estimated annual effective tax rate until 2013.

# 11. Employee Benefit Plans

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). Starting in 2012, the Company elected to match \$0.25 of every dollar on the first 4% of the employee's salary that is contributed to the plan. The Company did not elect to make any contributions to the 401(k) plan in 2011 and 2010.

# 12. Geographic Information

Revenues

Information regarding the Company's revenues by geographic area since it began sales in 2011 is as follows:

	December 31,						
		2012	2011				
	(in thousands)						
United States	\$	61,991	\$	21,511			
Ex - United States		39,538	•	122,749			
	\$	101,529	\$	144,260			

Does not include grant revenues.

# Long-lived Assets

Information regarding the Company's long-lived assets by geographic area is as follows:

	As of December 31,							
	2012		2011			2010		
United States	(in thousands)							
	\$	4,237	\$	2,358	\$	590		
Canada		52						
Taiwan		_		233		108		
Total	\$	4,289	\$	2,591	\$	698		

# 13. Quarterly Financial Data (Unaudited)

Selected quarterly consolidated financial data are shown below (in thousands, except per share data).

		First Quarter		Second Quarter		Third Quarter	 Fourth Quarter
2012 Quarters			-				
Total revenue	\$	14,383	\$	49,757	\$	17,876	\$ 19,515
Cost of product sales		1,217(1	)	1,484(1	).	1,421	1,364
Cost of contract revenue		1,068(1	)	2,530(1	)	1,213	1,652
Operating expenses		48,956		49,429	•	44,147	49,836
Income (loss) from operations		(34,573)		328		(26,272)	(30,320)
Gain on de-consolidation of OBI		23,782		*******			` _
Gain on sale of OBI shares		,		<del></del>			31,501
Loss related to equity method investment		(486)		(669)		(694)	·
Consolidated net income (loss)		(11,201)		(296)		(26,771)	1,001
Net income (loss) attributable to Optimer		. , , ,		` /			·
Pharmaceuticals, Inc. common stockholders	\$	(10,920)	\$	(296)	\$ .	(26,771)	\$ 1,001
Basic net income (loss) attributable to Optimer				` /			•
Pharmaceuticals, Inc. common stockholders	\$	(0.23)	\$	(0.01)	\$	(0.56)	\$ 0.02
Diluted net income (loss) attributable to Optimer	•	()	•	( )			
Pharmaceuticals, Inc. common stockholders	\$	(0.23)	\$	(0.01)	\$	(0.56)	\$ 0.02
	•	(32)	•	( , , ,	•	( )	
		First		Second		Third	Fourth
	_	Quarter		Quarter		Quarter	 Quarter
2011 Quarters							
Total revenue	\$	69,277	\$	33	\$	11,052	\$ 64,616
Operating expenses		24,458		25,051		37,966	51,864
Income (loss) from operations		44,819		(25,018)		(26,914)	12,752
Consolidated net income (loss)		44,842		(24,922)		(26,806)	12,815
Net income (loss) attributable to Optimer							
Pharmaceuticals, Inc. common stockholders	\$	45,133	\$	(24,239)	\$	(26,427)	\$ 13,354
Basic net income (loss) attributable to Optimer							
Pharmaceuticals, Inc. common stockholders	\$	1.06	\$	(0.52)	\$	(0.57)	\$ 0.29
Diluted net income (loss) attributable to Optimer							
Pharmaceuticals, Inc. common stockholders	\$	1.04	\$	(0.52)	\$	(0.57)	\$ 0.28

<sup>(1)</sup> Amount adjusted to reclassify cost of contracts from cost of product sales.

# 14. Subsequent Event

On February 26, 2013, the Board of Directors appointed Henry A. McKinnell, Ph.D., the Chairman of the Company's Board of Directors, as its Chief Executive Officer. Dr. McKinnell replaced Pedro Lichtinger, who served as the Company's President and Chief Executive Officer beginning in May 2010. The Board of Directors also appointed Meredith Schaum to replace Kurt Hartman as the Company's General Counsel and Chief Compliance Officer. The independent members of the Board of Directors recommended to the Board of Directors that the foregoing management changes were appropriate following their review of prior compliance, record keeping and conflict-of interest issues observed during the review, including issues arising from the conduct of its personnel who were

the subject of the changes in management and leadership announced in April 2012. The previously disclosed investigations of these issues by the relevant U.S. authorities are ongoing and the Company is continuing to cooperate with those authorities.

In connection with Mr. Lichtinger's resignation, the Company expects to enter into a separation agreement, pursuant to which Mr. Lichtinger will receive the following benefits: (i) an amount equal to 24 months of his base salary and a cash bonus based on 2012 performance, in each case less applicable tax withholdings; (ii) 24 months of continued group health benefits; and (iii) acceleration of 30,500 unvested restricted stock units and 230,292 unvested stock options with a weighted average exercise price of \$12.53.

In connection with Mr. Hartman's resignation, the Company entered into a separation agreement with Mr. Hartman, executed on March 2, 2013, pursuant to which Mr. Hartman will receive the following benefits: (i) an amount equal to 15 months of his base salary and a cash bonus based on 2012 performance, in each case, less applicable tax withholdings; (ii) 15 months of continued group health benefits; and (iii) acceleration of 1,167 unvested restricted stock units and 37,109 unvested stock options with a weighted average exercise price of \$10.18.

On February 27, 2013, the Company's Board of Directors announced that it had commenced a process to explore a full range of strategic alternatives, including a possible sale of the Company. In connection with this process, the Company have engaged J.P. Morgan and Centerview Partners as its financial advisers. In conjunction with this process, the Company's Board of Directors adopted a stockholder rights plan to protect its stockholders while the strategic review is being conducted.

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

- I, Henry A. McKinnell, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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 its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
- c) 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
- d) 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 18, 2013

/s/ Henry A. McKinnell
Henry A. McKinnell
Chief Executive Officer
(Principal Executive Officer)

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

- I, Stephen W. Webster, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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 its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
- c) 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
- d) 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 18, 2013

/s/ Stephen W. Webster
Stephen W. Webster
Chief Financial Officer
(Principal Financial and Accounting Officer)

# **CERTIFICATION**

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. § 1350, as adopted), Henry A. McKinnell, the Chief Executive Officer of Optimer Pharmaceuticals, Inc. (the "Company"), and Stephen W. Webster, 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, 2012, 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
- 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 18, 2013

/s/ Henry A. McKinnell
Henry A. McKinnell
Chief Executive Officer
(Principal Executive Officer)

/s/ Stephen W. Webster
Stephen W. Webster
Chief Financial 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 filing 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.

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# Optimer Pharmaceuticals, Inc.

# 101 Hudson Street, Suite 3501 Jersey City, NJ 07302

# NOTICE OF ANNUAL MEETING OF STOCKHOLDERS

### To Be Held On May 8, 2013

### Dear Stockholder:

You are cordially invited to attend the 2013 Annual Meeting of Stockholders of Optimer Pharmaceuticals, Inc., a Delaware corporation (the "Company"). The meeting will be held on Wednesday, May 8, 2013, at 8:00 a.m. Eastern Daylight time at the Grand Hyatt New York located at 109 East 42nd Street, New York, NY, 10017 for the following purposes:

- 1. To elect the three nominees for director named in the Proxy Statement to hold office until the 2016 Annual Meeting of Stockholders.
- 2. To ratify the selection by the Audit Committee of the Board of Directors of Ernst & Young LLP as our independent registered public accounting firm for our fiscal year ending December 31, 2013.
- 3. To approve, on an advisory basis, the compensation of the Company's named executive officers, as disclosed in the Proxy Statement.
- 4. To conduct any other business properly brought before the meeting.

These items of business are more fully described in the Proxy Statement accompanying this Notice.

The record date for the meeting is March 11, 2013. Only stockholders of record at the close of business on that date may vote at the meeting or any adjournment thereof.

By Order of the Board of Directors,

Henry A. McKinnell, Ph.D.

Chairman of the Board and Chief Executive Officer

Jersey City, New Jersey

April 12, 2013

You are cordially invited to attend the meeting in person. Whether or not you expect to attend the meeting, please complete, date, sign and return the enclosed proxy card as instructed in these materials, as promptly as possible in order to ensure your representation at the meeting. A return envelope (which is postage prepaid if mailed in the United States) is enclosed for your convenience. Even if you have voted by proxy, you may still vote in person if you attend the meeting. Please note, however, that if your shares are held of record by a broker, bank or other nominee and you wish to vote at the meeting, you must obtain a proxy issued in your name from that record holder.

Important Notice Regarding the Availability of Proxy Materials for the Stockholder Meeting to be Held on May 8, 2013. The Proxy Statement and our Annual Report on Form 10-K for the fiscal year ended December 31, 2012 are available at: http://viewproxy.com/optimerpharma/2013/.

# Optimer Pharmaceuticals, Inc. 101 Hudson Street, Suite 3501 Jersey City, NJ 07302

# PROXY STATEMENT FOR THE 2013 ANNUAL MEETING OF STOCKHOLDERS

# QUESTIONS AND ANSWERS ABOUT THIS PROXY MATERIAL AND VOTING

# Why am I receiving these materials?

We have sent you this proxy statement and the enclosed proxy card because the Board of Directors of Optimer Pharmaceuticals, Inc. (sometimes referred to as the "Company" or "Optimer") is soliciting your proxy to vote at the 2013 Annual Meeting of Stockholders (the "Annual Meeting"), including at any adjournments or postponements of the Annual Meeting. You are invited to attend the Annual Meeting to vote on the proposals described in this proxy statement. However, you do not need to attend the Annual Meeting to vote your shares. Instead, you may simply complete, sign and return the enclosed proxy card.

The Company intends to mail this proxy statement and accompanying proxy card on or about April 12, 2013 to all stockholders of record entitled to vote at the Annual Meeting.

# Who can vote at the Annual Meeting?

Only stockholders of record at the close of business on March 11, 2013 will be entitled to vote at the Annual Meeting. On this record date, there were 47,900,542 shares of common stock outstanding and entitled to vote.

Stockholder of Record: Shares Registered in Your Name

If at the close of business on March 11, 2013 your shares were registered directly in your name with our transfer agent, American Stock Transfer & Trust Company, then you are a stockholder of record. As a stockholder of record, you may vote in person at the Annual Meeting or vote by proxy. Whether or not you plan to attend the Annual Meeting, we urge you to fill out and return the enclosed proxy card.

Beneficial Owner: Shares Registered in the Name of a Broker, Bank or Other Nominee

If at the close of business on March 11, 2013 your shares were held, not in your name, but rather in an account at a brokerage firm, bank, dealer or other similar organization, then you are the beneficial owner of shares held in "street name" and these proxy materials are being forwarded to you by the organization holding your account. The organization holding your account is considered to be the stockholder of record for purposes of voting at the Annual Meeting. As a beneficial owner, you have the right to direct your broker or other agent regarding how to vote the shares in your account. You are also invited to attend the Annual Meeting. However, because you are not the stockholder of record, you may not vote your shares in person at the Annual Meeting unless you request and obtain a valid proxy from your broker or other agent.

# What matters will be voted on at the Annual Meeting?

There are three matters scheduled for a vote:

- Election of the three nominees for director named herein to hold office until the 2016 Annual Meeting of Stockholders;
- Ratification of Ernst & Young LLP as independent registered public accounting firm of the Company for its fiscal year ending December 31, 2013; and
- Advisory approval of the compensation of the Company's named executive officers, as disclosed in this proxy statement in accordance with Securities and Exchange Commission ("SEC") rules.

# What if another matter is properly brought before the Annual Meeting?

The Board of Directors knows of no other matters that will be presented for consideration at the Annual Meeting. If any other matters are properly brought before the Annual Meeting, it is the intention of the persons named in the accompanying proxy to vote on those matters in accordance with their best judgment.

### How do I vote?

You may either vote "For" each of the nominees to the Board of Directors named herein or you may "Withhold" your vote for any nominee you specify. For each of the other matters to be voted on, you may vote "For" or "Against" or abstain from voting. The procedures for voting are as follows:

Stockholder of Record: Shares Registered in Your Name

If you are a stockholder of record, you may vote in person at the Annual Meeting or vote by proxy using the enclosed proxy card. Whether or not you plan to attend the Annual Meeting, we urge you to vote by proxy to ensure your vote is counted. You may still attend the Annual Meeting and vote in person even if you have already voted by proxy.

- To vote in person, come to the Annual Meeting and we will give you a ballot when you arrive.
- To vote using the proxy card, complete, sign and date the enclosed proxy card and return it promptly in the envelope provided.

Beneficial Owner: Shares Registered in the Name of a Broker, Bank or Other Nominee

If you are a beneficial owner of shares registered in the name of your broker, bank or other agent, you should have received a proxy card and voting instructions with these proxy materials from that organization rather than from us. Simply complete and mail the proxy card to ensure that your vote is counted. To vote in person at the Annual Meeting, you must obtain a valid proxy from your broker, bank or other agent. Follow the instructions from your broker or bank included with these proxy materials, or contact your broker or bank to request a proxy form.

# How many votes do I have?

On each matter to be voted upon, you have one vote for each share of common stock you owned as of March 11, 2013.

# What if I return a proxy card but do not make specific choices?

If you return a signed and dated proxy card without marking any voting selections, your shares will be voted "For All" of the three nominees for director named herein, "For" the ratification of the selection by our Audit Committee of Ernst & Young LLP as our independent registered public accounting firm for our fiscal year ending December 31, 2013 and "For" the advisory approval of the compensation of the Company's named executive officers. If any other matter is properly presented at the Annual Meeting, your proxy (one of the individuals named on your proxy card) will vote your shares using his or her best judgment.

### Who is paying for this proxy solicitation?

We are paying for the distribution and solicitation of proxies. As a part of this process, we reimburse brokers, nominees, fiduciaries and other custodians for reasonable fees and expenses in forwarding proxy materials to our stockholders. In addition to these mailed proxy materials, our directors, employees and Alliance Advisors LLC may also solicit proxies in person, or by other means of communication. Directors and employees will not be paid any additional compensation for soliciting proxies, but Alliance Advisors LLC will be paid approximately \$6,500, plus out-of pocket expenses, to solicit proxies on our behalf.

### What does it mean if I receive more than one proxy card?

If you receive more than one proxy card, your shares are registered in more than one name or are registered in different accounts. Please complete, date, sign and return each proxy card to ensure that all of your shares are voted.

# Can I change my vote after submitting my proxy?

Yes. You can revoke your proxy at any time before the final vote at the Annual Meeting. If you are the record holder of your shares, you may revoke your proxy in any one of three ways:

- You may submit another properly completed proxy card with a later date to Optimer's Corporate Secretary at 101 Hudson Street, Suite 3501, Jersey City, NJ 07302.
- You may send a timely written notice that you are revoking your proxy to Optimer's Corporate Secretary at 101 Hudson Street, Suite 3501, Jersey City, NJ 07302.
- You may attend the Annual Meeting and vote in person. Simply attending the Annual Meeting will not, by itself, revoke your proxy.

If your shares are held by your broker or bank as a nominee or agent, you should follow the instructions provided by your broker or bank.

# When are stockholder proposals due for next year's Annual Meeting?

To be considered for inclusion in next year's proxy materials and/or considered at next year's Annual Meeting, a proposal must be submitted in writing by December 13, 2013, to Optimer Pharmaceuticals, Inc.; Attn: Corporate Secretary, 101 Hudson Street, Suite 3501, Jersey City, NJ 07302. If you wish to submit a proposal that is not to be included in next year's proxy materials or you wish to nominate a director, you must do so by December 13, 2013.

### How are votes counted?

Votes will be counted by the inspector of election appointed for the Annual Meeting, who will separately count, for the proposal to elect directors, "For" and "Withhold" votes and broker non-votes and, with respect to the other proposals, "For" and "Against" votes, abstentions and, if applicable, broker non-votes. Abstentions will be counted towards the vote total for each proposal, and will have the same effect as "Against" votes. Broker non-votes have no effect and will not be counted towards the vote total for any proposal.

### What are "broker non-votes"?

Broker non-votes occur when a beneficial owner of shares held in "street name" does not give instructions to the broker or nominee holding the shares as to how to vote on matters deemed "non-routine." Generally, if shares are held in street name, the beneficial owner of the shares is entitled to give voting instructions to the broker or nominee holding the shares. If the beneficial owner does not provide voting instructions, the broker or nominee can still vote the shares with respect to matters that are considered to be "routine," but not with respect to "non-routine" matters. Under applicable rules and interpretations of the New York Stock Exchange, "non-routine" matters are matters that may substantially affect the rights or privileges of stockholders, such as mergers, stockholder proposals, elections of directors (even if not contested) and executive compensation, including advisory stockholder votes on executive compensation.

# How many votes are needed to approve each proposal?

- For the election of directors, the three nominees receiving the most "For" votes from the holders of shares present in person or represented by proxy and entitled to vote on the election of directors will be elected. Only votes "For All" or "Withhold All" or "For All Except" will affect the outcome. Broker non-votes will have no effect.
- To be approved, Proposal No. 2, ratification of Ernst & Young LLP as independent registered public accounting firm of the Company for its fiscal year ending December 31, 2013, must receive "For" votes from the holders of a majority of shares present and entitled to vote at the Annual Meeting either in person or by proxy. If you "Abstain" from voting, it will have the same effect as an "Against" vote.
- Proposal No. 3, advisory approval of the compensation of the Company's named executive officers, will be considered to be approved if it receives "For" votes from the holders of a majority of shares present and entitled to vote at the Annual Meeting either in person or by proxy. If you "Abstain" from voting, it will have the same effect as an "Against" vote. Broker non-votes will have no effect.

# What is the quorum requirement?

A quorum of stockholders is necessary to hold a valid meeting. A quorum will be present if a majority of the issued and outstanding shares are represented at the meeting in person or by proxy. At the close of business on the record date, there were 47,900,542 shares outstanding and entitled to vote. Thus, the holders of at least 23,950,272 shares must be represented in person or by proxy to have a quorum.

Your shares will be counted toward the quorum only if you submit a valid proxy (or one is submitted on your behalf by your broker, bank or other nominee) or if you vote in person at the meeting. Abstentions and broker non-votes will be counted toward the quorum requirement. If there is no quorum, the chairperson of the Annual Meeting or the holders of a majority of shares present at the Annual Meeting may adjourn the Annual Meeting to another date.

# How can I find out the results of the voting at the Annual Meeting?

Preliminary voting results will be announced at the Annual Meeting. In addition, final voting results will be published in a current report on Form 8-K that we expect to file within four business days after the Annual Meeting. If final voting results are not available to us in time to file a Form 8-K within four business days after the Annual Meeting, we intend to file a Form 8-K to publish preliminary results and, within four business days after the final results are known to us, file an additional Form 8-K to publish the final results.

# PROPOSAL 1

### **ELECTION OF DIRECTORS**

Our Board of Directors is divided into three classes. Each class consists, as nearly as possible, of one-third of the total number of directors, and each class has a three-year term. Vacancies on the Board of Directors may be filled by persons elected by a majority of the remaining directors. A director elected by the Board of Directors to fill a vacancy in a class, including a vacancy created by an increase in the number of directors, shall serve for the remainder of the full term of that class and until the director's successor is elected and qualified.

As a result of Mr. Lichtinger's resignation in February 2013, the Board of Directors presently has eight members. Although fewer nominees are named than the number fixed in accordance with our bylaws, proxies cannot be voted for a greater number of persons than the number of nominees named. The Board of Directors may elect additional members in the future in accordance with our bylaws. There are three directors in the class whose term of office expires in 2013. Each of the nominees listed below is currently a director of the Company. Mr. Mark Auerbach and Dr. Joseph Y. Chang were previously elected by the stockholders and Dr. Stephen L. Newman was appointed by our Board of Directors in July 2012. If elected at the Annual Meeting, each of these nominees would serve until the 2016 Annual Meeting and until his successor is elected and has qualified, or, if sooner, until the director's death, resignation or removal. It is the Company's policy to encourage directors and nominees for director to attend the Annual Meeting. All of our directors except for Drs. Joseph Chang and Michael Chang attended the 2012 Annual Meeting of Stockholders. Directors are elected by a plurality of the votes of the holders of shares present in person or represented by proxy and entitled to vote on the election of directors. The three nominees receiving the highest number of affirmative votes will be elected. Shares represented by executed proxies will be voted, if authority to do so is not withheld, for the election of the three nominees named below. If any nominee becomes unavailable for election as a result of an unexpected occurrence, shares that would have been voted for that nominee will instead be voted for the election of a substitute nominee proposed by Optimer. Each person nominated for election has agreed to serve if elected. Our management has no reason to believe that any nominee will be unable to serve.

The following is a brief biography of each nominee and each director whose term will continue after the Annual Meeting and a discussion of the specific experience, qualifications, attributes or skills of each person that led the Compensation, Nominating and Corporate Governance Committee to recommend that person as a nominee for director and that qualify such person to continue as a director, respectively, as of the date of this proxy statement.

# NOMINEES FOR ELECTION FOR A THREE-YEAR TERM EXPIRING AT THE 2016 ANNUAL MEETING

### Mark Auerbach

Mr. Auerbach, 74, has served as a director and Chairman of the Audit Committee since June 2005 and has served as our Lead Independent Director since February 2013. Over the last 20 years, Mr. Auerbach has served as a director for several companies. Since 2010, Mr. Auerbach has served as a director, including as the current Chairman of the Audit Committee, of Ventrus Bioscience, Inc., a development-stage specialty pharmaceutical company focused on the development of late-stage prescription drugs for gastrointestinal disorders. From January 2006 through March 2010, Mr. Auerbach served as the Chairman of the Board of Directors for Neuro-Hitech, Inc., an early-stage pharmaceutical company that specializes in brain degenerative diseases. From June 2007 through August 2009, he served as a director for Collexis Holdings, Inc., a company that develops knowledge management and discovery software. From July 2007 through February 2009, Mr. Auerbach served as director for RxElite Holdings, Inc., a company that develops, manufactures and markets generic prescription drug products in specialty generic markets. Mr. Auerbach received a B.S. degree in accounting from Rider University. Mr. Auerbach's demonstrated leadership in his field, his knowledge of finance and his experience in general business and financing matters contribute to our conclusion that he should continue to serve as a director.

# Joseph Y. Chang, Ph.D.

Dr. Joseph Chang, 60, has served as a director since November 1998. Dr. Joseph Chang has served as the Chief Scientific Officer and Executive Vice President of Nu Skin Enterprises Inc., a publicly-traded personal care and nutritional supplement company, since February 2006. Dr. Joseph Chang also served as the President of Pharmanex, Nu Skin Enterprises' nutritional supplement division, from April 2000 to February 2006. Dr. Joseph Chang served as Vice President of Clinical Studies and Pharmacology of Pharmanex from 1997 until April 2000. From 1994 until 1997, he was the President and Chief Scientific Officer of Binary Therapeutics, Inc., a development-stage company in the biotechnology industry. Dr. Joseph Chang received a B.S. degree from Portsmouth University and a Ph.D. degree from the University of London. Dr. Joseph Chang is not related to Dr. Michael Chang, who is also a director of the Company. Dr. Joseph Chang's demonstrated leadership in his field, his knowledge of scientific matters affecting our business and his understanding of our industry contribute to our conclusion that he should continue to serve as a director.

# Stephen L. Newman, M.D.

Dr. Newman, 62, has served as a director since July 2012. Dr. Newman served in various capacities at Tenet Healthcare Corporation, a health care delivery and services company, from 1999 to 2012, including serving as Vice Chairman from January 2012 until his retirement in June 2012. Dr. Newman served as Chief Operating Officer of Tenet Healthcare Corporation from January 2007 through December 2011. Dr. Newman also served as Chief Executive Officer of Tenet's California region from February 2003 through December 2006. Before joining Tenet, Dr. Newman held executive positions at Columbia/HCA Inc. from April 1997 to February 1999 and served as Senior Vice President and Chief Medical Officer of Touro Infirmary in New Orleans from August 1990 to March 1997. Prior to 1990, Dr. Newman served as Associate Professor of Pediatrics and Medicine at Wright State University School of Medicine and as Director of Gastroenterology and Nutrition Support at the Children's Medical Center in Dayton, Ohio. Dr. Newman recently completed a five-year term on the Board of Directors of the Federation of American Hospitals and currently serves on the Labor, Education and Healthcare Advisory Committee of the Federal Reserve Bank of Atlanta. Since July 2012, Dr. Newman has served as a director of Hansen Medical, Inc., a biotechnology company, and since March 2013, Dr. Newman has served as a director of Cadence Pharmaceuticals, Inc., a biopharmaceutical company. Dr. Newman holds a Bachelor's degree from Rutgers University, an M.B.A. from Tulane University and a medical degree from the University of Tennessee. He completed his internship, residency and fellowship at Emory University School of Medicine. Dr. Newman also completed the Advanced Management Program at the University of Pennsylvania's Wharton School of Business. Dr. Newman's demonstrated leadership in his field, his knowledge of scientific matters affecting our business and his understanding of our industry contribute to our conclusion that he should continue to serve as a director.

THE BOARD OF DIRECTORS RECOMMENDS A VOTE IN FAVOR OF EACH NAMED NOMINEE.

# DIRECTORS CONTINUING IN OFFICE UNTIL THE 2014 ANNUAL MEETING

### Anthony E. Altig

Mr. Altig, 57, has served as a director since November 2007 and currently serves as the Chairman of the Compensation, Nominating and Corporate Governance Committee. Mr. Altig has served as the Chief Financial Officer at Biotix Holdings, Inc., a company that manufactures microbiological consumables, since 2008. From 2004 to 2007, Mr. Altig served as the Chief Financial Officer of Diversa Corporation (subsequently Verenium Corporation), a publicly-traded company developing specialized industrial enzymes. Prior to joining Diversa, Mr. Altig served as the Chief Financial Officer of Maxim Pharmaceuticals, Inc., a publicly-traded biopharmaceutical company, from 2002 to 2004. In addition to these and other corporate positions, Mr. Altig served as a consultant to the biotechnology and technology industry during his tenure at both PricewaterhouseCoopers LLP and KPMG LLP. In addition, Mr. Altig serves as a director and Chairman of the Audit Committee for TearLab Corporation, a publicly-traded health care company focused on evidence-based ophthalmic devices for the diagnosis and treatment of age related eye diseases, and served as a director and Chairman of the Audit Committee for MultiCell Technologies, Inc., a publicly-traded biopharmaceutical company, until September 2012. Mr. Altig recently began serving as a director of Ventrus Biosciences, Inc., a development-stage specialty pharmaceutical company focused on the development of late-stage prescription drugs for gastrointestinal disorders. Mr. Altig received a B.B.A. degree from the University of Hawaii. Mr. Altig's demonstrated leadership in his field, his knowledge of finance and his experience in financing matters contribute to our conclusion that he should serve as a director.

# Michael N. Chang, Ph.D.

Dr. Michael Chang, 62, has served as a director since our inception in November 1998, served as the Chairman of our Board of Directors until April 2012 and served as our President and Chief Executive Officer from November 1998 to May 2010. From November 1998 to January 2000, Dr. Michael Chang was the Chief Scientific Officer of Nu Skin Enterprises, Inc., a publicly-traded personal care and nutritional supplement company. Dr. Michael Chang joined Nu Skin Enterprises upon its acquisition of Pharmanex, Inc., a natural healthcare company, which he founded and where he was employed beginning in January 1995 as Senior Vice President, Research and Development and Chief Science Officer. Before Pharmanex, Dr. Michael Chang worked for 15 years in the pharmaceutical industry, at Merck & Co, Inc., a publicly-traded pharmaceutical company, Rhone-Poulenc Rorer Inc., which is now Sanofi-Aventis, a publicly-traded pharmaceutical company, and ArQule, Inc., a development-stage oncology company. Dr. Michael Chang received a B.S. degree in chemistry from Fu-Jen University in Taiwan, a Ph.D. degree in organic chemistry from Brandeis University and post-doctoral training at the Massachusetts Institute of Technology. Dr. Michael Chang is married to Tessie M. Che, Ph.D., who prior to her retirement in January 2012 was our Chief Operating Officer. Dr. Michael Chang is not related to Dr. Joseph Chang, who is also a director of the Company. Dr. Michael Chang's demonstrated leadership in his field, his prior senior management experience in our industry and his prior experience as our Chief Executive Officer contributed to our prior conclusion that he should serve as a director. However, due to the views of our Board of Directors regarding Dr. Michael Chang's actions in his capacity as our representative on the board of directors of our former subsidiary, Optimer Biotechnology, Inc. ("OBI") as well as his failure to identify and effectively manage compliance, record keeping and conflict of interest issues, our Board of Directors removed Dr. Michael Chang as the Chairman of our Board of Directors in April 2012 and requested that Dr. Michael Chang resign from the Board of Directors, which he has not.

# Robert L. Zerbe, M.D.

Dr. Zerbe, 62, has served as a director since December 2009. Dr. Zerbe currently serves as Chief Executive Officer and President at QuatRx Pharmaceutical Company, a private biopharmaceutical company he co-founded in 2000. Prior to founding QuatRx, Dr. Zerbe served as Senior Vice President of Worldwide Clinical Research and Development at Warner-Lambert Company, a pharmaceutical company, during which time he oversaw the successful development programs of Lipitor®, Neurotin® and other products. Prior to joining Warner-Lambert Company, Dr. Zerbe held a variety of research and development positions, including Vice President of Clinical Investigation and Regulatory Affairs at Eli Lilly and Company, a pharmaceutical company, in the United States and the United Kingdom. Dr. Zerbe also serves on the board of directors of Aastrom Biosciences, Inc., a clinical development-stage company. Dr. Zerbe earned his medical degree at Indiana University and received his post graduate training in internal medicine, endocrinology and neuroendocrinology at Indiana University and the National Institutes of Mental Health. Dr. Zerbe's demonstrated leadership in his field, his understanding of our industry and his prior senior management experience contribute to our conclusion that he should serve as a director.

# DIRECTORS CONTINUING IN OFFICE UNTIL THE 2015 ANNUAL MEETING

# Peter E. Grebow, Ph.D.

Dr. Grebow, 66, has served as a director since February 2009. Since March 2011, Dr. Grebow has been employed by P.E. Grebow Consulting, Inc. From January 1991 to February 2011, Dr. Grebow held several key positions with Cephalon, Inc., a biopharmaceutical company, including Executive Vice President, Cephalon Ventures, Executive Vice President, Technical Operations, Senior Vice President, Worldwide Business Development and Senior Vice President, Drug Development. Prior to joining Cephalon, Dr. Grebow served as the Vice President, Drug Development for Rorer Central Research, a division of Rhone-Poulenc Rorer Pharmaceuticals Inc., a pharmaceutical company, from 1988 to 1990. Dr. Grebow was appointed as a director of Q Holdings, Inc., an emerging biopharmaceutical company that utilizes cell-based technologies to develop new treatments for debilitating diseases of the central nervous system in December of 2011. Additionally, Dr. Grebow serves as a director of GenSpera, Inc., a development-stage pharmaceutical company focused on the development of prodrug cancer therapeutics for the treatment of solid tumors including prostate, liver, brain and other cancers. Dr. Grebow received his undergraduate degree from Cornell University, a Masters of Science in Chemistry from Rutgers University and a Ph.D. in Physical Biochemistry from the University of California, Santa Barbara. Dr. Grebow's demonstrated leadership in his field, his knowledge of scientific matters affecting our business and his understanding of our industry contribute to our conclusion that he should serve as a director.

# Henry A. McKinnell, Ph.D.

Dr. McKinnell, 70, has served as our Chief Executive Officer since February 2013, as a director since January 2011 and served as our Lead Independent Director from February 2012 until he was appointed as the Chairman of our Board of Directors in April 2012. Dr. McKinnell served as Chairman of the Board of Pfizer Inc., a pharmaceutical company, from May 2001 until his retirement in December 2006 and Chief Executive Officer from January 2001 to July 2006. Dr. McKinnell currently serves as Chairman of the Board of Directors of Moody's Corporation. Dr. McKinnell also serves as Chairman of the Board of the Accordia Global Health Foundation. He is Chairman Emeritus of the Connecticut Science Center and is a member of the Academic Alliance for AIDS Care and Prevention in Africa. Dr. McKinnell also served as director of ExxonMobil Corporation from 2002 until 2007 and served as a director of John Wiley & Sons from 1996 until 2005. Dr. McKinnell holds a Bachelor's degree in business from the University of British Columbia, and M.B.A. and Ph.D. degrees from the Stanford University Graduate School of Business. Dr. McKinnell's demonstrated leadership in the pharmaceutical field, including development and commercialization activities and his prior senior management experience contribute to our conclusion that he should serve as a director.

# INFORMATION REGARDING THE BOARD OF DIRECTORS AND CORPORATE GOVERNANCE

# **Independence of the Board of Directors**

Under the listing standards of the Nasdaq Global Select Market ("NASDAQ"), a majority of the members of a listed company's Board of Directors must qualify as "independent," as affirmatively determined by the Board of Directors. The Board of Directors consults with the Company's counsel to ensure that the Board of Directors' determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in pertinent NASDAQ listing standards, as in effect from time to time.

Consistent with these considerations, after review of all relevant transactions and relationships between each current director and former director who served during 2012, or any of his family members, and Optimer, its senior management and its independent registered public accounting firm, the Board of Directors has affirmatively determined that each of our directors that served during 2012 was an independent director within the meaning of the applicable NASDAQ listing standards, except for Mr. Lichtinger, our former director, President and Chief Executive Officer and Dr. Michael Chang. Mr. Lichtinger and Dr. Michael Chang did not qualify as independent directors by virtue of their employment and consultancy, respectively, with the Company in 2012. Dr. Michael Chang's consultancy with the Company was terminated in April 2012.

The Board of Directors has affirmatively determined that each of our current directors is independent within the meaning of the applicable NASDAQ listing standards, except for Drs. Michael Chang and McKinnell. Dr. Michael Chang does not qualify as independent by virtue of the consultancy agreement described above. Dr. McKinnell was an independent director within the meaning of the applicable NASDAQ listing standards until his appointment as our Chief Executive Officer on February 26, 2013. In making these independence determinations, the Board of Directors found that none of the independent directors or nominees for director had a material or other disqualifying relationship with us.

# **Board of Directors Leadership Structure**

Dr. McKinnell is currently our Chief Executive Officer and the Chairman of the Board of Directors. He has served as Chairman since April 2012 and as Chief Executive Officer since February 2013. The Board of Directors believes that Dr. McKinnell is well qualified to serve in these roles because of his demonstrated leadership in the pharmaceutical field, including development and commercialization activities, his prior senior management experience and his past role as the Chairman of the Board of Directors of Pfizer Inc. In connection with Dr. McKinnell's appointment as our Chief Executive Officer in February 2013, Mr. Auerbach was appointed as our Lead Independent Director.

# **Lead Independent Director**

As Lead Independent Director, Mr. Auerbach leads all meetings of the non-management directors held in executive session. In addition, the Lead Independent Director has the following responsibilities: with the Chief Executive Officer, establish the agenda for regular Board of Directors meetings; establish the agenda for meetings of the independent directors; coordinate with the committee chairmen regarding meeting agendas and informational requirements; preside over executive sessions and other meetings of the independent directors; preside over any portions of meetings of the Board of Directors at which the evaluation or compensation of the Chief Executive Officer is presented or discussed; preside over any portions of meetings of the Board of Directors at which the performance of the Board of Directors is presented or discussed; convey any messages from meetings of the independent directors to the Chief Executive Officer; be available to discuss with other directors any concerns he or she may have about the Company and its performance and relay these concerns, where appropriate, to the full Board of Directors or the Chief Executive Officer; and be available to consult with senior executives of the Company.

# Role of the Board of Directors in Risk Oversight

The entire Board of Directors, and each of its committees, are involved in overseeing risk associated with the Company. The Board of Directors and the Audit Committee monitor the Company's liquidity risk, regulatory risk, operational risk, enterprise risk and credit risk by conducting regular reviews with management, external auditors and other advisors. The Audit Committee works with management in its review of accounting and financial controls, assessment of business risks and legal and ethical compliance programs. The Audit Committee also periodically meets with the external auditors and discusses the scope and results of the relevant audits. In July 2012, the Audit Committee approved the engagement of Eisner Amper to conduct certain internal audits and report directly to the Audit Committee. The Board of Directors and the Compensation, Nominating and Corporate Governance Committee monitor the Company's governance risk, succession risk and the Company's compensation policies and related risks by conducting regular reviews with management as well as outside advisors.

#### **Meetings of the Board of Directors**

The Board of Directors met 11 times during the 2012 fiscal year. In addition, the independent directors have been meeting as needed in connection with the internal investigation disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2012. Each Board member attended 75% or more of the aggregate of the meetings of the Board of Directors, and of the committees on which he served, held during the period for which he was a director or committee member.

# **Information Regarding Committees of the Board of Directors**

The Board of Directors has two standing committees: an Audit Committee and a Compensation, Nominating and Corporate Governance Committee. Prior to the decision of the Board of Directors in May 2012 to reconstitute the standing committees, the Board of Directors had four standing committees: an Audit Committee, a Compensation Committee, a Nominating and Corporate Governance Committee and a Strategy and Science Committee. The following table provides current membership information and meeting information for the 2012 fiscal year for each of the Board committees:

		Compensation,
		Nominating and
		Corporate
Name	Audit	Governance
Anthony E. Altig	X	X*
Mark Auerbach	X*	X
Joseph Y. Chang	$\mathbf{X}$	X
Michael N. Chang		
Peter E. Grebow	X	X
Henry A. McKinnell (1)		
Stephen L. Newman	X	X
Robert L. Zerbe	X	$\mathbf{X}$
Total meetings in fiscal 2012 (2)	9	4 (3)

\* Committee Chairperson

(1) Resigned from the Audit Committee and the Compensation, Nominating and Corporate Governance Committee in February 2013 in connection with his appointment as our Chief Executive Officer.

(2) The Strategy and Science Committee did not meet in 2012 and was disbanded in May 2012 in connection with the reconstitution of the standing committees.

(3) In addition to the meetings of the Compensation, Nominating and Corporate Governance Committee, prior to the reconstitution of the standing committees, from January 1, 2012 until May 9, 2012, the Compensation Committee met six times and the Nominating and Corporate Governance Committee met two times. The Compensation, Nominating and Corporate Governance Committee also has a standing sub-committee, the Inducement Award Sub-Committee. This sub-committee met once in 2012.

Below is a description of each committee of the Board of Directors. The Board of Directors has determined that each member of the Audit Committee and the Compensation, Nominating and Corporate Governance Committee qualifies as "independent" under the applicable NASDAQ rules and regulations and that each such member is free of any relationship that would impair his exercise of independent judgment with regard to the Company.

#### Audit Committee

The Audit Committee was established by the Board of Directors in accordance with Section 3(a)(58)(A) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and oversees the Company's corporate accounting and financial reporting process. For this purpose, the Audit Committee performs several functions. Among other things, the Audit Committee evaluates the performance of, and assesses the qualifications of, the independent registered public accounting firm; determines whether to retain or terminate the existing independent registered public accounting firm or to appoint and engage a new independent registered public accounting firm; approves all audit engagement fees and the terms of all non-audit engagements; confers with management and the independent registered public accounting firm regarding the effectiveness of internal controls over financial reporting; establishes procedures, as required under applicable law, for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls or auditing matters and the confidential and anonymous submission by employees of concerns regarding questionable accounting or auditing matters; reviews the financial statements to be included in our Annual Report on Form 10-K; and discusses with management and our independent registered public accounting firm the results of the annual audit and the results of the Company's quarterly financial statements.

Currently, the Audit Committee is comprised of six directors: Messrs. Auerbach and Altig, and Drs. Joseph Chang, Grebow, Newman and Zerbe. Mr. Auerbach is the Chairman of the Audit Committee. Our Board of Directors has determined that Messrs. Auerbach and Altig and Dr. Zerbe qualify as independent directors and "audit committee financial experts," as defined in the applicable rules of the SEC. Our Board of Directors made a qualitative assessment of each Audit Committee member's level of knowledge and experience based on a number of factors, including their formal education and prior work experience.

The Audit Committee has adopted a written charter that is available on the Company's website at www.optimerpharma.com and met nine times during the fiscal year ended December 31, 2012.

# Report of the Audit Committee of the Board of Directors

The Audit Committee has reviewed and discussed the audited financial statements for the fiscal year ended December 31, 2012, with the Company's management. The Audit Committee has discussed with the independent registered public accounting firm the matters required to be discussed by the Statement on Auditing Standards No. 61, as amended (AICPA, Professional Standards, Vol. 1, AU section 380), as adopted by the Public Company Accounting Oversight Board ("PCAOB") in Rule 3200T. The Audit Committee has also received the written disclosures and the letter from the independent registered public accounting firm required by applicable requirements of the PCAOB regarding the independent accounting firm's communications with the Audit Committee concerning independence, and has discussed with the independent registered public accounting firm the independent accountants' independence. Based on the foregoing, the Audit Committee has recommended to the Board of Directors that the audited financial statements be included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2012.

**AUDIT COMMITTEE** 

Mr. Mark Auerbach

Mr. Anthony E. Altig

Dr. Joseph Y. Chang

Dr. Peter E. Grebow

Dr. Stephen L. Newman

Dr. Robert L. Zerbe

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

# Compensation, Nominating and Corporate Governance Committee

Currently, the Compensation, Nominating and Corporate Governance Committee consists of Messrs. Auerbach and Altig, and Drs. Joseph Chang, Grebow, Newman and Zerbe. The functions of this committee include, among other things:

- evaluating and approving material compensation plans and programs applicable to the Company's executive officers and directors, as well as modifications and terminations of such plans and programs;
- administering the Company's compensation plans and programs, establishing guidelines under such plans and programs, interpreting plan documents, selecting participants, approving grants and awards and exercising such other power and authority as may be permitted or required under such plans;
- reviewing (in consultation with the Board of Directors) and approving corporate goals and objectives relevant to the compensation of the Chief Executive Officer and the Company's other executive officers, and evaluating their performance in light thereof;
- reviewing and approving the terms of any employment agreements, severance arrangements, change-of-control protections and any other compensatory arrangements for the Company's executive officers;
- reviewing and approving the type and amount of compensation to be paid or awarded to Board of Directors members;
- evaluating the current composition, organization and governance of the Board of Directors and its committees;
- evaluating and selecting nominees for election to the Board of Directors;
- evaluating the performance of and, if appropriate, recommending termination of particular directors in accordance with the Board of Directors' governance principles;
- developing and recommending to the Board of Directors a set of corporate governance principles applicable to the Company and periodically reviewing such principles and recommending to the Board of Directors appropriate changes; and
- reviewing with the Chief Executive Officer the plans for succession of each of the Company's executive officers.

The Compensation, Nominating and Corporate Governance Committee has adopted a written charter that is available on the Company's website at www.optimerpharma.com and met four times from May 9, 2012 to December 31, 2012. Prior to the decision of the Board of Directors in May 2012 to reconstitute the standing committees, the Compensation Committee and the Nominating and Corporate Governance Committee met six times and two times, respectively, during the fiscal year ended December 31, 2012. Mr. Altig serves as the Chairman of the Compensation, Nominating and Corporate Governance Committee.

The Compensation, Nominating and Corporate Governance Committee has the authority to engage the services of outside advisors to provide support and guidance on our compensation program. In 2012, the Compensation, Nominating and Corporate Governance Committee retained Radford, an Aon Hewitt Company ("Radford"), as its independent compensation consultant. Radford reviewed our pay philosophy and peer group to ensure appropriateness, analyzed and recommended our peer group, assessed our executive compensation program and developed recommendations for base salary, bonus and long-term incentive compensation, assessed our director cash and equity compensation program to ensure alignment with market practices, reviewed the compensation landscape with the Compensation, Nominating and Corporate Governance Committee highlighting changes and upcoming potential changes and participated in other specific projects as needed such as a review of severance and change-in-control arrangements and an assessment of broad-based equity programs below the senior level.

The Compensation, Nominating and Corporate Governance Committee uses many sources to identify potential director candidates, including the network of contacts among our directors, officers and other employees, and may engage outside consultants and recruiters in this process. As set forth below under "Stockholder Director Recommendations," the Compensation, Nominating and Corporate Governance Committee will consider director candidates recommended by our stockholders. The Compensation. Nominating and Corporate Governance Committee believes that candidates for director should have certain minimum qualifications, including knowledge of the biopharmaceutical industry and being able to understand basic financial statements. The Compensation, Nominating and Corporate Governance Committee will consider all relevant factors, which may include, among others, the candidate's experience and accomplishments, the usefulness of such experience to our business, the availability of the candidate to devote sufficient time and attention to Optimer, the candidate's reputation for integrity and ethics and the candidate's ability to exercise sound business judgment. In the case of incumbent directors, our Compensation, Nominating and Corporate Governance Committee reviews each director's overall service to the Company during their term, including the number of meetings attended, level of participation, quality of performance and any other relationships and transactions that might impair such director's independence. In the case of new director candidates, the Compensation, Nominating and Corporate Governance Committee also determines whether the nominee must be independent for NASDAQ purposes, which determination is based upon applicable NASDAQ listing standards. applicable SEC rules and regulations and the advice of counsel, if necessary. In addition, although we do not have a formal policy on diversity, the Compensation, Nominating and Corporate Governance Committee believes that Board of Directors should represent diverse experience at policy-making levels in business, education and technology, and in areas that are relevant to our business activities. The Compensation, Nominating and Corporate Governance Committee retains the right to modify these qualifications from time to time, and candidates for director are reviewed in the context of the composition of the then current Board of Directors, our requirements and the interests of our stockholders. The Compensation, Nominating and Corporate Governance Committee recommended the nominations of each of the directors nominated for election at the Annual Meeting.

# Compensation, Nominating and Corporate Governance Committee Interlocks and Insider Participation

No member of our Compensation, Nominating and Corporate Governance Committee (or the Compensation Committee prior to May 9, 2012) has ever concurrently been an executive officer or employee of ours. During 2012, Dr. McKinnell served on our Compensation, Nominating and Corporate Governance Committee. In connection with his appointment as our Chief Executive Officer in February 2013, Dr. McKinnell resigned from our Compensation, Nominating and Corporate Governance Committee. None of our executive officers currently serves, or has served during the last completed fiscal year, on the compensation committee or board of directors of any other entity that has one or more executive officers serving as a member of our Board of Directors or Compensation, Nominating and Corporate Governance Committee (or the Compensation Committee prior to May 9, 2012).

# Compensation, Nominating and Corporate Governance Committee Report

The Compensation, Nominating and Corporate Governance Committee has reviewed and discussed with management the Compensation Discussion and Analysis contained in this proxy statement. Based on this review and discussion, the Compensation, Nominating and Corporate Governance Committee has recommended that the Compensation Discussion and Analysis be included in this proxy statement and incorporated into our Annual Report on Form 10-K for the fiscal year ended December 31, 2012.

COMPENSATION, NOMINATING AND CORPORATE GOVERNANCE

**COMMITTEE** 

Mr. Mark Auerbach

Mr. Anthony E. Altig

Dr. Joseph Y. Chang

Dr. Peter E. Grebow

Dr. Stephen L. Newman

Dr. Robert L. Zerbe

The material in this report is not "soliciting material," is not deemed "filed" with the SEC and is not to be incorporated by reference in any filing of the Company under the Securities Act or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

# **Stockholder Director Recommendations**

The Compensation, Nominating and Corporate Governance Committee will consider director candidates recommended by our stockholders. A candidate must be highly qualified and be willing and expressly interested in serving on our Board of Directors. The Compensation, Nominating and Corporate Governance Committee does not intend to alter the manner in which it evaluates candidates, including the minimum criteria set forth above, based on whether the candidate was recommended by a stockholder. To be considered by the Compensation, Nominating and Corporate Governance Committee, a stockholder recommendation for director candidates for the 2014 Annual Meeting of Stockholders must be received by the committee by December 13, 2013. A stockholder who wishes to recommend a candidate for the Compensation, Nominating and Corporate Governance Committee's consideration should forward the candidate's name and information about the candidate's qualifications to our Corporate Secretary, Optimer Pharmaceuticals, Inc., 101 Hudson Street, Suite 3501, Jersey City, NJ 07302. Submissions must include a representation that the nominating stockholder is a beneficial or record owner of our stock. Any such submission must be accompanied by the written consent of the proposed nominee to be named as a nominee and to serve as a director if elected. This procedure does not affect the deadline for submitting other stockholder proposals for inclusion in the proxy statement, nor does it apply to questions a stockholder may wish to ask at an annual meeting. Additional information regarding submitting stockholder proposals is set forth in our bylaws. Stockholders may request a copy of the bylaw provisions relating to stockholder proposals from our Corporate Secretary at Optimer Pharmaceuticals, Inc., 101 Hudson Street, Suite 3501, Jersey City, NJ 07302.

# Stockholder Communications with the Board of Directors

Our Board of Directors has a formal process by which stockholders may communicate with our Board of Directors or any of our directors or officers. Stockholders who wish to communicate with our Board of Directors or any of our directors or officers may do so by sending written communications addressed to such person or persons in care of our Corporate Secretary, Optimer Pharmaceuticals, Inc., 101 Hudson Street, Suite 3501, Jersey City, NJ 07302. The Company's Corporate Secretary shall compile and submit the communications to the addressees on a periodic basis. If our Board of Directors modifies this process, we will post the revised process on our website.

# **Code of Ethics**

We have adopted a Code of Business Conduct and Ethics that applies to all of our officers, directors and employees. The Code of Business Conduct and Ethics is available on our website at www.optimerpharma.com. We will promptly disclose on our website (i) the nature of any amendment to the Code of Business Conduct and Ethics 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 Code of Business Conduct and Ethics 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.

# COMPENSATION AND OTHER INFORMATION CONCERNING EXECUTIVE OFFICERS, DIRECTORS AND CERTAIN STOCKHOLDERS

Our executive officers and directors and their respective ages and positions are as follows:

	Age	Position					
Name  II A Makingall Dh D	70	Chief Executive Officer and Chairman of the Board					
Henry A. McKinnell, Ph.D.	56	Senior Vice President, Human Resources					
Linda E. Amper, Ph.D	78	Senior Vice President, Chief Scientific Officer					
Sherwood L. Gorbach, M.D	37	General Counsel, Chief Compliance Officer and Secretary					
Meredith Schaum		Chief Financial Officer					
Stephen W. Webster	52						
Anthony E. Altig	57	Director					
Mark Auerbach	74	Director					
Joseph Y. Chang, Ph.D	60	Director					
Michael N. Chang, Ph.D.	62	Director					
Peter E. Grebow, Ph.D.	66	Director					
Stephen L. Newman, M.D	62	Director					
Robert L. Zerbe, M.D.	62	Director					

# **Executive Officers**

Henry A McKinnell, Ph.D., has served as our Chief Executive Officer since February 2013, as a director since January 2011 and served as our Lead Independent Director from February 2012 until he was appointed as the Chairman of our Board of Directors in April 2012. Dr. McKinnell served as Chairman of the Board of Pfizer Inc., a pharmaceutical company, from May 2001 until his retirement in December 2006 and Chief Executive Officer from January 2001 to July 2006. Dr. McKinnell currently serves as Chairman of the Board of Directors of Moody's Corporation. Dr. McKinnell also serves as Chairman of the Board of the Academic Alliance for Global Health Foundation. He is Chairman Emeritus of the Connecticut Science Center and is a member of the Academic Alliance for AIDS Care and Prevention in Africa. Dr. McKinnell also served as director of ExxonMobil Corporation from 2002 until 2007 and served as a director of John Wiley & Sons from 1996 until 2005. Dr. McKinnell holds a Bachelor's degree in business from the University of British Columbia, and M.B.A. and Ph.D. degrees from the Stanford University Graduate School of Business.

Linda E. Amper, Ph.D., has served as our Senior Vice President of Human Resources since January 2011. Dr. Amper has over 20 years of experience in human resources. Prior to joining Optimer, from 2001 to 2010, Dr. Amper was the Senior Vice President, Human Resources at OSI Pharmaceuticals (now Astellas Pharma), a biotechnology company primarily focused on the discovery, development and commercialization of molecular-targeted therapies addressing medical needs in oncology, diabetes and obesity. From 1978 to 2001, Dr. Amper served at the New York Blood Center, where she held several key positions including her final position as Executive Director and Vice President of Long Island Blood Services, a division of the New York Blood Center and, just prior, as Vice President, Human Resources for the New York Blood Center. Dr. Amper holds a Ph.D. in philosophy, health administration from Columbia Southern, a Master of Public Administration with a specialization in health care from Long Island University, Post, and a B.S. in medical biology from Long Island University, Post.

Sherwood L. Gorbach, M.D., joined us as our Senior Vice President, Medical Affairs and Chief Medical Officer in November 2005 and has served as our Senior Vice President, Chief Scientific Officer since February 2011. In addition to serving on the faculties of The Johns Hopkins University, the University of Illinois and UCLA, Dr. Gorbach has been at Tufts University School of Medicine since 1975 as, among other things, Professor of Medicine, Public Health and Community Health and a Professor in the School of Nutrition and Social Policy. Dr. Gorbach was also Chief of Infectious Diseases at the New England Medical Center from 1975 to 1987. In 1990, he served as the President of the Massachusetts Infectious Diseases Society, and in 1995, he was the President of the Society of Microbial Ecology and Disease. Dr. Gorbach received the Lifetime Achievement Award in Recognition of Exemplary Dedication and Leadership at the 3rd Congress on Anaerobic Bacteria and Infectious Diseases Society of America. In 2008, he received a Lifetime Achievement Award from the Anaerobe Society of the Americas and in 2009 he received the Tufts University Alumni Association Distinguished Service Award. He has served as editor of the Clinical Infectious Diseases Journal for the past twelve years. Dr. Gorbach received his M.D. at the Tufts University School of Medicine.

Meredith Schaum, has served as our General Counsel, Chief Compliance Officer and Secretary since February 2013, and served as our Senior Corporate Counsel from January 2012 to February 2013. Prior to joining Optimer, Ms. Schaum was an associate at the law firm of Dechert LLP from May 2005 to December 2011 and previously was an associate at the law firm of Skadden, Arps, Slate, Meagher & Flom LLP and Affiliates from 2000 to 2005. Ms. Schaum holds a B.A. in Political Science from Villanova University and received her J.D. from the University of Pennsylvania Law School.

Stephen W. Webster, has served as our Chief Financial Officer since June 2012. Prior to joining Optimer, Mr. Webster served as the Chief Financial Officer of Adolor Corporation from June 2008 until its acquisition by Cubist Pharmaceuticals, Inc. in December 2011. From 2007 until joining Adolor Corporation in 2008, Mr. Webster served as Managing Director, Investment Banking Division, Health Care Group for Broadpoint Capital (formerly First Albany Capital). Mr. Webster previously served as cofounder, President and Chief Executive Officer for Neuronyx, Inc., a biopharmaceutical company. From 1987 to 2000, Mr. Webster served in positions of increased responsibility, including as Director, Investment Banking Division, Health Care Group for PaineWebber Incorporated. Mr. Webster holds an A.B. in Economics cum laude from Dartmouth College and a Master of Business Administration in Finance from The Wharton School of the University of Pennsylvania.

# COMPENSATION DISCUSSION AND ANALYSIS

# **Executive Summary**

This Compensation Discussion and Analysis discusses 2012 compensation for our "named executive officers," including our former Chief Executive Officer, our Chief Financial Officer and other executive officers. The highlights of the discussion include:

- Strong link between pay and performance. In 2012, we saw an increased demand for DIFICID®, with "sales revenue" (defined as GAAP U.S. product sales, net) rising from \$21.5 million in 2011 to \$62.0 million in 2012. We also made progress in our efforts to establish collaborations and distribution arrangements in international markets and, through our research and development program, continued to explore opportunities to expand the DIFICID label. While these developments were positive, 2012 sales revenue did not reach the target level included as a key performance metric in our named executive officers' performance-based restricted stock units and performance cash bonus opportunity for 2012. As a result, performance-based restricted stock units granted in 2012 were earned at 0% of target and were cancelled. Furthermore, performance cash bonuses for 2012, which included the 2012 sales revenue metric as well as other corporate and personal metrics, were earned between 38% and 65% of target and were down an average of 43% in dollar terms for named executive officers who received a cash bonus for both 2012 and 2011. We believe that this demonstrates a strong link between pay and performance in our executive compensation program.
- High ratio of performance-based compensation. For our named executive officers who were employed throughout 2012, an average of 63% of direct compensation paid or awarded for 2012, measured by target grant value or target bonus opportunity, was performance-based. For our former Chief Executive Officer, 80% was performance-based. For these executives, an average of 33% of direct compensation for 2012 was in the form of performance restricted stock units and performance cash bonuses, which were at risk if threshold levels of performance were not met and were ultimately forfeited or earned at below-target levels, as described above. An average of an additional 26% of direct compensation for 2012 was in the form of stock options from which the executives will realize value only if the price of our common stock increases over time.
- Improved corporate governance. In 2012, we adopted stock ownership guidelines for our executive officers and directors that require the accumulation and maintenance of a substantial interest in our common stock. These guidelines help to align the interests of our executive officers and directors with those of our stockholders. We also changed our compensation benchmarking from between the 50th and 60th percentile of our peer group to the 50th percentile. Finally, following a review of prior compliance, recordkeeping and conflict-of-interest issues by the independent members of our Board of Directors, we made certain management changes in 2012 and the first quarter of 2013.

These and other topics are discussed in more detail below.

#### Introduction

The year 2012 and the first quarter of 2013 represented a period of significant management transition for Optimer. In April 2012, we removed Dr. Michael Chang as the Chairman of our Board of Directors and requested that he resign from the Board, which he has not done. Also in April 2012, the Board of Directors terminated the employment of John D. Prunty, our then-Chief Financial Officer, and Dr. Youe-Kong Shue, our then-Vice President, Clinical Development. On February 26, 2013, Pedro Lichtinger, who had served as our President and Chief Executive Officer since May 2010, stepped down and was succeeded as Chief Executive Officer by the Chairman of our Board of Directors, Dr. McKinnell. In connection with Dr. McKinnell's appointment, the Board of Directors appointed Mr. Auerbach, who has served on our Board of Directors since June 2005, as Lead Independent Director. In addition, also on February 26, 2013, Kurt Hartman stepped down as our General Counsel and Chief Compliance Officer and was succeeded by Ms. Schaum, previously Senior Corporate Counsel to Optimer. The independent members of our Board of Directors recommended to the Board of Directors that these management changes were appropriate following a review of prior compliance, recordkeeping and conflict-of-interest issues.

In accordance with SEC requirements, this Compensation Discussion and Analysis describes the compensation earned in 2012 by Mr. Lichtinger (our President and Chief Executive Officer at the end of 2012), Stephen W. Webster (our Chief Financial Officer at the end of 2012) and our three executive officers at the end of 2012 who were the most highly compensated for the year: Dr. Amper (Senior Vice President, Human Resources), Dr. Gorbach (Senior Vice President, Chief Scientific Officer) and Mr. Hartman (General Counsel and Chief Compliance Officer at the end of 2012). In addition, this Compensation Discussion and Analysis also describes the compensation earned in 2012 by Mr. Prunty, our former Senior Vice President, Chief Financial Officer, whose employment with us terminated in April 2012, and Gregory E. Papaz, our former Senior Vice President, U.S. Commercial Operations, whose employment with us terminated in December 2012. We refer to the foregoing individuals, collectively, as our "named executive officers."

# Objectives and Philosophy of Executive Compensation

Our executive compensation program was formerly overseen by the Compensation Committee of our Board of Directors, which was combined with our former Nominating and Corporate Governance Committee of our Board of Directors in May 2012, as described elsewhere in this proxy statement, and is currently overseen by the combined Compensation, Nominating and Corporate Governance Committee of our Board of Directors. In this Compensation Discussion and Analysis, references to the "Committee" are to the Compensation Committee with respect to compensation decisions made through May 9, 2012 and to the Compensation, Nominating and Corporate Governance Committee with respect to compensation decisions following May 9, 2012. The primary objectives of the Committee with respect to executive compensation are to attract and retain the most talented and dedicated executives possible and to structure annual and long-term cash and stock incentives according to a philosophy of pay-for-performance. To achieve these objectives, the Committee develops and maintains compensation plans that tie a material portion of executives' overall compensation to key strategic financial and operational goals, such as achievement of target sales revenue, advancement in research and development and establishment of key strategic relationships. The Committee sets individual executive compensation at levels the Committee believes are competitive with those executives in other companies of a similar size and stage of development operating in the biotechnology and pharmaceutical industry based on the process described below, while taking into account our relative performance and our own strategic goals.

We conduct an annual benchmark review of our executive compensation. This review is conducted by Radford, our external compensation consultant, and provided to the Committee for discussion and analysis. This review primarily analyzes and compares annual base salaries, cash bonuses and equity awards to our peer group. We also take into account data available in the Radford Global Life Sciences Survey (the "Radford Survey"), which is a nationally recognized assessment of executive compensation widely used within the pharmaceutical industry.

In August 2011, Radford reviewed our historical peer companies to determine if they were still viable, considering merger and acquisition activity, change in financial profile or business focus and projected changes in our own profile. Radford identified other potential comparator companies in our market space, which included identifying all publicly-traded, U.S.-based companies in the pharmaceutical and biopharmaceutical industries and refining the list based generally on targeted criteria of stage of development (commercial or late Phase 3), employee size (50-500) and market value (\$150 million to \$2 billion). Radford qualitatively evaluated each company based on business focus and corporate strategy to determine its appropriateness as a peer and recommended select companies most similar to us with regard to financial profile and industry focus. The peer group ultimately selected by the Committee in 2011, which was used to make compensation decisions for 2012, was comprised of the companies below.

Acorda Therapeutics, Inc. Avanir Pharmaceuticals, Inc. GTx, Inc. Momenta Pharmaceuticals, Inc.

Allos Therapeutics, Inc. Cadence Pharmaceuticals, Inc. Halozyme Therapeutics, Inc. OPKO Health, Inc.

AMAG Pharmaceuticals, Inc. Cell Therapeutics, Inc. InterMune, Inc. Savient Pharmaceuticals, Inc.

ARIAD Pharmaceuticals, Inc. Dyax Corp. MAP Pharmaceuticals, Inc. Spectrum Pharmaceuticals, Inc.

In August 2012, Radford again reviewed our historical peer companies, following the process described above. After identifying other potential comparator companies in our market space, Radford refined the list based on stage of development (commercial), employee size (100-1,000), trailing four quarter revenue (less than \$300 million) and market value (\$200 million to \$2.2 billion). As in 2011, Radford qualitatively evaluated each company based on business focus and corporate strategy to determine its appropriateness as a peer and recommended select companies most similar to us with regard to financial profile and industry focus. The peer group ultimately selected by the Committee in 2012, which was used to assess current compensation and to plan changes for 2013, was comprised of the companies below.

Acorda Therapeutics, Inc. Emergent BioSolutions Inc. MAP Pharmaceuticals, Inc. Santarus, Inc.

Akorn, Inc. Halozyme Therapeutics, Inc. Momenta Pharmaceuticals, Inc. SciClone Pharmaceuticals, Inc.

ARIAD Pharmaceuticals, Inc. Incyte Corporation Nektar Therapeutics Spectrum Pharmaceuticals, Inc.

Auxilium Pharmaceuticals, Inc. InterMune, Inc. OPKO Health, Inc. Theravance, Inc.

Avanir Pharmaceuticals, Inc. Isis Pharmaceuticals, Inc. Questcor Pharmaceuticals, Inc. ViroPharma Incorporated

Dyax Corp. Jazz Pharmaceuticals plc

We benchmark the base salaries, equity holdings and target cash bonuses of our executive officers against the compensation for similarly-situated executives reported in the Radford Survey and in our peer group. We currently benchmark at the 50th percentile, although in 2011 and for the majority of 2012 we benchmarked between the 50th and 60th percentiles. The Committee believed that a transition to benchmarking at the 50th percentile was appropriate to better reflect Optimer's commitment to pay-for-performance and best practices on corporate governance. We believe that the companies in the Radford Survey and in our peer group provide us with appropriate compensation benchmarks for base salaries, equity holdings and target cash bonuses because these companies are in the same industry, are of similar size and tend to compete with us for executives. The Committee believes that this benchmarking is, therefore, an important means of achieving one of its primary objectives of attracting and retaining the best executives.

In order to achieve the other primary objective of maintaining a pay-for-performance compensation program, the Committee uses performance-based equity compensation and cash incentives. As described more fully below, the Committee designs these elements of compensation to motivate our executive officers to achieve important corporate and individual goals that it believes will drive company performance and, ultimately, enhance stockholder value. As a result of its analysis of equity grants and corporate performance, in February 2012, the Committee awarded stock options and performance-based restricted stock units to our executives under our 2006 Equity Incentive Plan. Restricted stock units represent the right to receive shares of our common stock in the future after the shares vest. We believe that restricted stock units are an important component of our compensation package that reflect our pay-for-performance philosophy by allowing the executive to benefit from our achievement of key strategic financial and operational goals and increases in the price of our common stock. The performance-based restricted stock units granted in February 2012 were subject to achievement of a 2012 target sales revenue goal that was not met, as described in more detail below. Accordingly, those restricted stock units were cancelled. In February 2013, the Committee awarded stock options and performance-based restricted stock units to our executives under our 2012 Equity Incentive Plan.

# The Role of Stockholder Say-on-Pay Votes

Last year, we provided our stockholders with the opportunity to cast an advisory vote on executive compensation. At our Annual Meeting of Stockholders held in May 2012, a majority (78%) of the votes cast on the say-on-pay proposal at that meeting were in favor of the proposal. Prior to the say-on-pay vote, the Committee reviewed our compensation approach and concluded it would be strengthened by the use of performance-based equity awards. For that reason, the Committee determined to issue a combination of options and performance-based restricted stock units to executives, including our named executive officers, in 2012, as described

above. The Committee is using a similar approach in 2013 and will continue to consider the outcome of our say-on-pay votes when making future compensation decisions for our named executive officers.

# **Elements of Executive Compensation**

Executive compensation consists of the following elements:

# **Base Salary**

The initial base salaries for our executives are established at the time of hire, taking into account the executive officer's scope of responsibilities, qualifications, experience, competitive salary information and compensation of our similarly-situated employees. Base salaries for ensuing years are determined based on an assessment of the executive's performance against job responsibilities, overall company performance, merit increase survey data and competitive salary information of similarly sized pharmaceutical companies. For purposes of setting base salary levels, the Committee considers both the executive's demonstrated value to the organization and its business, as well as his or her anticipated contributions to the success (both short-term and long-term) of the Company. Base salaries are reviewed annually, and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience and our benchmarking analysis. This review occurs promptly after the fourth quarter with the annual adjustment in base salaries, if any, made effective as of January 1. In the first quarter of 2012, the Committee conducted its annual review and adjusted executive base salaries accordingly. The following base salary increases for our named executive officers were approved by the Committee: Mr. Lichtinger from \$505,248 to \$567,000, Dr. Amper from \$310,000 to \$323,000, Dr. Gorbach from \$310,000 to \$320,000, Mr. Papaz from \$310,000 to \$323,000, Mr. Prunty from \$310,000 to \$320,000, and Mr. Hartman from \$260,000 to \$310,000.

# Performance-based Cash Incentives

We use cash incentive awards to reinforce our performance-based compensation policy. On February 7, 2012, the Committee adopted the Optimer Pharmaceuticals, Inc. Incentive Compensation Plan (the "Incentive Bonus Plan"). The Incentive Bonus Plan provides for the payment of cash bonuses to our executive officers and all other employees that do not participate in a sales incentive bonus or commission plan. Under the Incentive Bonus Plan, each participant is assigned a target bonus equal to a percentage of annual base salary. Actual bonuses paid under the Incentive Bonus Plan are based on the achievement of preestablished corporate and individual goals. Any bonus paid to our Chief Executive Officer under the Incentive Bonus Plan is based entirely on the achievement of corporate goals. Of any bonus paid under the Incentive Bonus Plan to any of our senior vice presidents or executive officers, 75% is based on corporate goals and 25% is based on individual goals. All participants have the same corporate goals, which are recommended by our Chief Executive Officer and Chief Financial Officer each year and reviewed and approved by the Committee. Individual goals for our executive officers are established each year by our Chief Executive Officer upon consultation with senior staff. The degree to which corporate goals have been met is determined by the Committee and the degree to which individual goals have been met is, with respect to our officers, recommended by our Chief Executive Officer and approved by the Committee and, with respect to all other Incentive Bonus Plan participants, is recommended by the applicable department head and approved by our Chief Executive Officer and the Committee, in all cases after the end of our applicable fiscal year. The Committee has the discretion to grant awards that exceed the target awards in the case of exemplary achievement or eliminate or reduce awards below the amount otherwise determined by multiplying the target award amount by the applicable "goal achievement percentage."

The corporate goals for 2012 related to the following categories at the relative weightings indicated, which were based on the Committee's assessment of the relative importance of each category to the Company's overall performance: (i) the U.S. DIFICID commercialization effort (including field-based promotion, educational efforts, publications, meetings with key hospitals, access strategy and generating at least \$107 million in sales revenue in 2012), weighted at 50%; (ii) the international DIFICID launch effort (launching DIFICID in EU markets and executing against market entry strategy for other key international markets), weighted at 20%; (iii) research and development (including implementation of a plan to meet regulatory requirements, beginning label expansion and life-cycle management work and submitting a multiple recurrence trial protocol to FDA), weighted at 20%; and (iv) business development (including planning in-licensing of a hospital product or product candidate to leverage market investment, establishing a robust strategy to maximize value to shareholders and putting in place a strategy to respond to a potential hostile acquisition attempt) and financial management (including monitoring investment levels to achieve a dynamic resource allocation over the year, managing expenses in line with budget and monitoring cash flow needs), weighted at 10%.

Individual goals were tailored for each executive officer based on our business plan for 2012 and the Chief Executive Officer's recommendations. The individual goals of our named executive officers for 2012 related to the following categories: (i) progress and milestones for commercialization of DIFICID; (ii) ensuring successful commercialization of DIFICID; (iii) medical education and publications; (iv) finance, including the completion of fundraisings, as appropriate, filing SEC documents and managing cash burn to within budget; (v) compliance and risk mitigation; (vi) corporate governance, including supporting the recruitment of new members of our Board of Directors, as necessary; (vii) corporate planning; (viii) strategic opportunities, including

creating value through partnering and evaluating in-licensing opportunities; (ix) intellectual property; and (x) investor and analyst relations, including attending investor conferences and non-deal road shows, engaging in regular telephonic communications and issuing timely press releases.

Corporate and individual goals were intended to reflect a mix of short- and long-term performance objectives. We typically expect the level of achievement of each goal to fall in the upper end of the scale. The Committee believes that the corporate goals it approved for 2012 were stretch goals, but achievable goals, set in a manner to motivate the Company's executives and other participants to advance corporate performance and create stockholder value. In acknowledgment of the challenges that the Company faced in 2012, the Committee determined that the corporate goal component was achieved at a 50% level, while the individual component of the goals was determined to be achieved in most cases at a 100% level.

All of our named executive officers participated in the Incentive Bonus Plan. The following table lists our named executive officers, their incentive target under the plan expressed as a percentage of their annual base salary and the relative weighting assigned to corporate and individual goals:

		Relative Weighting		
Named Executive Officer	Incentive Target	Corporate Goals	Individual Goals	
Pedro Lichtinger	65%	100%	<del></del>	
Stephen W. Webster	40%	75%	25%	
Kurt M. Hartman	40%	75%	25%	
John D. Prunty	40%	75%	25%	
Linda E. Amper	40%	.75%	25%	
Sherwood L. Gorbach, M.D.	40%	75%	25%	
Gregory E. Papaz	40%	75%	25%	

For Incentive Bonus Plan participants, both corporate and individual goals, as applicable, must be achieved at a minimum 50% level for any award to be paid. In determining corporate goal achievement, the Committee considered both actual achievement against the previously established goals, as well as any changes in the Company's circumstances and strategic direction which impacted achievement in ways that the Committee believed were outside of the executive officers' control. Based on these considerations, the Committee determined that: (i) the U.S. DIFICID commercialization goal was not met, resulting in 0% achievement; (ii) the international DIFICID launch goal was exceeded, resulting in 125% achievement; (iii) the research and development goal was met at the 100% level; and (iv) the business development and financial management goal was met at the 50% level. As noted above, the weighted value of these outcomes resulted in an overall 50% achievement of the 2012 corporate objectives under the Incentive Bonus Plan. With regard to the 2012 individual goals, the Committee, based upon a review of individual performance, determined that Mr. Webster and Dr. Gorbach achieved 100% of the weighted value of their individual goals and Dr. Amper achieved 110% of the weighted value of her individual goals. Pursuant to the terms of his offer letter, discussed below under "Employment and Change-in-control Arrangements," Mr. Webster's bonus was not prorated. The Committee determined that Mr. Hartman would not be eligible for the portion of his bonus attributable to his individual goals due to his resignation in February 2013. As noted above, Mr. Lichtinger had no individual goals and the determination of his bonus was based entirely on the achievement of corporate goals. Accordingly, the named executive officers received bonuses in the following amounts: Mr. Lichtinger — \$184,275; Dr. Amper — \$83,980; Dr. Gorbach — \$82,500; Mr. Hartman — \$46,500; Mr. Webster — \$91,250.

# Long-term Incentive Program

We believe that long-term performance is achieved through an ownership culture that encourages such performance by our executive officers through the use of stock and stock-based awards. Our stock plans provide the principal method for our executive officers to acquire equity in the Company and have been established to provide our employees, including our executive officers, with incentives to help align those employees' interests with the interests of stockholders. The Committee believes that the use of stock and stock-based awards offers the best approach to achieving our long-term compensation goals. We have historically elected to use stock options as the primary long-term equity incentive vehicle. We recently broadened the use of restricted stock units and, to our executives, performance-based restricted stock units. For our named executive officers, we target an annual mix of long-term incentive compensation of 50% stock options and 50% performance-based restricted stock units (based on grant date fair market value of the award and, for the grants made in February 2012, a conversion from options to performance-based restricted stock units at a value-neutral rate of 1.48 options per restricted stock unit). We believe that granting such awards allows our executives to benefit from our achievement of key strategic financial and operational goals and increases executive alignment with our shareholders. We believe that the annual aggregate value of these awards should be set near competitive median levels for comparable companies.

The following are the principal reasons we use stock-based awards as a long-term incentive vehicle:

- Stock-based awards align the interests of executives with those of our stockholders, foster employee stock ownership and focus the management team on increasing value for our stockholders.
- Vesting of performance-based restricted stock units are specifically tied to the level of sales revenue attained and are subject to cancellation if a threshold level of sales revenue is not achieved. In addition, we believe that stock options are performance-based because the value received by the recipient from a stock option is based entirely on the increase of our stock price.
- Stock-based awards help to provide a balance to the overall executive compensation program. Base salary and our annual incentive bonus plan focus on short-term compensation, while the vesting provisions of stock-based awards focus on long-term compensation.
- The vesting period of stock-based awards encourages executive retention.

Performance-based Restricted Stock Units. The Committee oversees the administration of our 2012 Equity Incentive Plan. The Committee reviews and approves stock awards, including stock-based performance awards such as performance-based restricted stock units, to executive officers based upon a review of competitive compensation data, its assessment of individual performance, a review of each executive's existing long-term incentives and retention considerations. The 2012 Equity Incentive Plan allows us to grant stock-based performance awards that may be granted, vest or be exercised based upon the attainment during a specified period of time of specified performance goals. The length of any performance period, the performance goals to be achieved during the performance period and the measure of whether and to what degree such performance goals have been attained will be determined by the Committee, or to the extent that the award is not intended to comply with Section 162(m) of the Internal Revenue Code, as amended (the "Internal Revenue Code"), by the Board of Directors. Performance goals may be on a company-wide basis or with respect to one or more business units, divisions, affiliates or business segments, and may be in absolute terms or may be relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Performance-based restricted stock units may be granted under the 2012 Equity Incentive Plan at the commencement of employment and, from time to time thereafter, following a significant change in job responsibilities, to meet other special retention objectives or for other reasons the Committee deems appropriate. In February 2012, in keeping with our philosophy of pay-for-performance, we initiated a practice of granting performance-based restricted stock units to our executives, including our named executive officers other than Mr. Webster, who received a grant of performance-based restricted stock units upon the commencement of his employment in June 2012. If the Company achieved a threshold level of sales revenue for the fiscal year 2012, as determined by the Committee, then a pro-rata portion of the performance-based restricted stock units (based on the percentage at which the target was achieved but not to exceed 100%) would vest one-third on the date of determination and one-third on each of January 1, 2014 and January 1, 2015. If the Company did not achieve at least 75% of the sales revenue target, then the award would be cancelled. Any unvested performance-based restricted stock units will be subject to forfeiture to the extent the recipient's service with us terminates prior to vesting.

For the 2012 grant, the target level of sales revenue for 2012 was set at \$107 million, consistent with the U.S. DIFICID commercialization goal for 2012. The Company achieved sales revenue of \$62.0 million for 2012, which was less than 75% of the sales revenue target. Accordingly, the performance-based restricted stock units granted in February 2012 (and to Mr. Webster in June 2012) were cancelled.

Stock Options. Our 2012 Equity Incentive Plan authorizes us to grant options to purchase shares of common stock to our employees, directors and consultants. Stock options granted by us have an exercise price equal to the fair market value of our common stock on the day of grant, typically vest over a four-year period with 25% vesting twelve months after the vesting commencement date and the remainder vesting ratably each month thereafter based upon continued employment and generally expire ten years after the date of grant. Incentive stock options also include certain other terms necessary to assure compliance with the Internal Revenue Code. In February 2012, we granted time-vested stock options to our named executive officers other than Mr. Webster, who received a grant of time-vested stock options upon the commencement of his employment in June 2012.

Time-vested Restricted Stock Units. Our 2012 Equity Incentive Plan authorizes us to grant time-vested restricted stock units, representing a right to receive one share of the Company's common stock (subject to adjustment for certain specified changes in our capital structure) per restricted stock unit upon the completion of a specified period of continued service. In June 2012, we made a new-hire grant of time-vested restricted stock units to Mr. Webster, which will vest in one-third installments on each of the first, second and third anniversaries of the commencement of his employment, subject to his continued employment with us. In August 2012, in recognition of the procurement of a New Technology Add-on Payment for DIFICID, we made a one-time grant of time-vested restricted stock units to Dr. Gorbach, which will vest in one-third installments on each of the first, second and third

anniversaries of the vesting commencement date, subject to his continued employment with us. Mr. Hartman also received such a grant, a portion of which has been canceled due to the termination of his employment.

Employee Stock Purchase Plan. We have adopted an employee stock purchase plan as a further benefit to our employees, including our named executive officers, and to encourage employee stock ownership. Under the employee stock purchase plan, participants may elect to have a portion of their cash compensation withheld to purchase our common stock on certain dates set forth in the plan. The price of our common stock purchased under our employee stock purchase plan is equal to 85% of the lower of the fair market value of our common stock on the date of enrollment or the exercise date of the purchase period. The offering periods commence on the first trading day on or after May 15 and November 15 of each year.

# New Hire Bonus for Mr. Webster

Mr. Webster joined Optimer as our Chief Financial Officer in June 2012. In connection with the commencement of his employment, in addition to the equity grants described above, Mr. Webster received a new hire cash bonus of \$50,000.

# 2013 Transition Arrangements

On February 26, 2013, the Board appointed Dr. McKinnell as our Chief Executive Officer. Dr. McKinnell will be entitled to receive: (i) a base salary of \$1.00 per year; (ii) stock options to purchase up to 225,000 shares of our common stock which will vest over four years from February 26, 2013; and (iii) 60,000 performance-based restricted stock units, which vest over time beginning on the date we achieve a specified financial goal. In addition, Messrs. Lichtinger and Hartman resigned and, other than the 2012 compensation described above, each received solely the severance benefits to which they were entitled under their pre-existing arrangements. These benefits are described under "Potential Payments Upon Termination or Change-in-control Transition Arrangements" below. Each of Messrs. Lichtinger and Hartman has agreed to repay any amounts and benefits he receives in connection with his resignation in the event that a court finally determines that he engaged in any act for which he would not be entitled to indemnification under Section 8.1 of our bylaws.

#### Risk Assessment

We believe our approach to goal setting, setting of targets with payouts at multiple levels of performance and evaluation of performance results assists the Company in preventing excessive risk-taking that could harm our value or reward poor judgment by our executives and rewards sound risk management practices. For example, the Committee considers changes in circumstances when evaluating corporate goal achievement under our incentive compensation plan, so as not to encourage the pursuit of goals that are no longer thought to be consistent with the Company's strategic direction or best interests. Further, with respect to our incentive compensation programs, a substantial majority (75%) of the metrics that determine payouts for most of our executive officers are company-wide metrics. This is based on our belief that applying company-wide metrics encourages decision-making that is in the best long-term interests of the Company and our stockholders as a whole. The mix of equity award instruments used under our long-term incentive program also mitigates risk. Finally, the multi-year vesting of our equity awards properly accounts for the time horizon of risk.

# Other Compensation

Consistent with our compensation philosophy, we maintain general benefits for all of our full-time employees, including medical, dental, vision, long-term disability and life insurance coverage and the ability to contribute to a 401(k) retirement plan; however, the Committee in its discretion may revise, amend or add to these benefits if it deems it advisable.

# Change-in-control and Severance Arrangements

We maintain the Optimer Amended and Restated Severance Benefit Plan (the "Severance Plan") covering certain eligible employees, including our named executive officers. Pursuant to the Severance Plan, upon an involuntary termination other than for cause, an eligible employee may be entitled to receive specified severance benefits. The benefits may include continuation of base salary and a percentage of bonus payments, acceleration of stock award vesting as well as continuing medical benefits. The level of benefits provided under the Severance Plan depends upon an eligible employee's position and whether the termination is related to a "change of control" as defined in the Severance Plan. In adopting severance and change-in-control arrangements, the Committee considered that executives, especially highly-ranked executives, often face challenges securing new employment following termination, and that termination often occurs following a change-in-control transaction. The Committee believes, therefore, that these severance arrangements help us attract and retain the best executive officers and will also help keep our executive officers focused on our and our stockholders' best interests during any change-in-control transaction. The Severance Plan was amended

effective May 5, 2010, and further amended and restated in each of February 2012 and February 2013. Additional details about these severance provisions, including definitions of "cause" and "change of control" and a description of the 2013 amendments, can be found under "Potential Payments Upon Termination or Change-in-control," below.

### **Compensation Consultant**

Radford serves as compensation consultant at the sole discretion of, and reports directly to, the Committee. Radford does not provide any other services to the Company and has provided the Committee with information from which the Committee has confirmed Radford's independence. In its role as compensation consultant, Radford analyzes compensation programs nationwide, assists the Committee in selecting appropriate peers and advises the Company on the alignment of its total compensation plan to market and current best governance practices.

# Management Participation

The Chief Executive Officer makes recommendations to the Committee regarding compensation decisions, including achievement of individual performance goals, with respect to his direct reports. The Committee considers these recommendations and makes final determinations. The compensation of the Chief Executive Officer is determined by our Board of Directors.

# **EXECUTIVE COMPENSATION**

The following table provides information regarding the compensation earned during the fiscal years ended December 31, 2012, 2011 and 2010 by our named executive officers.

# **SUMMARY COMPENSATION TABLE**

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$) (1)	Option Awards (\$) (1)	Non-equity Incentive Plan Compensation (\$) (2)	All Other Compensati on (\$)	Total (\$)
Pedro Lichtinger,								
Former President, Chief Executive	2012	567,000		1,134,840(4)	1,017,468(5)	184,275	373,577(6)	3,277,160
Officer and Director (3)	2011	505,248		401,340(7)	420,222	328,125		1,654,935
	2010	295,095	100,000(8)	740,400(9)	3,614,555(10)	157,000	69,649(11)	4,976,699
Stephen W. Webster								
Chief Financial Officer	2012	189,519	50,000(12)	618,400(13)	975,130(5)	91,250	80,000(14)	2,004,298
John D. Prunty,			* * .					
Former Senior Vice President.	2012	86,154	·	337,750(4)	296,762(5)		284,760(15)	1,005,426
Chief Financial Officer and	2011	309,998	_	151,650(16)	289,808	128,844	204,700(13)	880,300
Corporate Secretary	2010	259,619		——————————————————————————————————————	231,501	93,000	<del>_</del> .	584,120
Kurt Hartman, Former Chief Financial Officer.	2012	310,000		235,445(18)	158,979(5)	46,500		750 004
Chief Compliance Officer and General Counsel (17)	2012	310,000	_	233,443(18)	130,979(3)	40,300		750,924
Linda E. Amper, Ph.D.								
Senior Vice President, Human	2012	323,000		182,385(4)	158,979(5)	83,980		748,344
Resources (19)	2012	296,089	50,000(20)	162,565( <del>1</del> )	724,520	128,844	7,500(21)	1,206,953
		,				,	, , ,	, , ,
Sherwood Gorbach, M.D.,								
Senior Vice President, Chief	2012	330,000		53,060(18)	206,207(5)	82,500		671,767
Scientific Officer	2011	310,000			289,808	128,844	_	728,652
	2010	260,100	* A		207,446	95,000	· —	562,546
Gregory E. Papaz,								
Former Senior Vice President, U.S.	2012	302,088	_	182,385(4)	158,979(5)		41,120(23)	684,572
Commercial Operations (22)	2011	310,000	. —		725,160	128,844	4,495(24)	1,168,499
	_							

Amounts shown reflect aggregate full grant date fair value of restricted stock units or option awards granted during the year in accordance with FASB ASC Topic 718. Pursuant to FASB ASC Topic 718, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. For additional information on the valuation assumptions underlying the value of these restricted stock units and options, see Part II, Item 8 "Financial Statements and Supplementary Data" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2012 in the Notes to Consolidated Financial Statements, Note 8, "Stockholders Equity."

<sup>(2)</sup> For 2012, represents awards approved under the Incentive Bonus Plan. For 2011 and 2010, represents awards approved under the Company's 2011 or 2010 Incentive Compensation Plan, as applicable.

- (3) Mr. Lichtinger was hired in May 2010. In connection with his resignation in February 2013, Mr. Lichtinger entered into a separation agreement providing for the acceleration or cancellation of certain equity awards as described in more detail under "Potential Payments Upon Termination or Change-in-control— Employment Agreement and Transition Arrangements."
- (4) Represents the grant date fair value of the maximum number of shares underlying a performance-based restricted stock unit award that was canceled because the performance goal was not met.
- (5) Represents the grant date fair value of time-vested stock options granted under our 2012 Equity Incentive Plan.
- (6) Represents reimbursement of closing costs incurred with respect to the 2012 sale of Mr. Lichtinger's home in connection with his 2010 relocation.
- (7) Includes the fair value of a performance-based restricted stock unit granted by the Company and providing for future delivery by the Company of 450,000 common shares of OBI in the amount of \$151,650 and the fair value of a non-performance-based restricted stock unit award in the amount of \$249,690. The restricted stock unit relating to the 450,000 common shares of OBI was cancelled in May 2012 as described in more detail under "Transactions with Related Persons."
- (8) Represents a sign-on bonus Mr. Lichtinger received in connection with the start of his employment.
- (9) Represents the grant date fair value of four performance-based restricted stock units covering an aggregate of 120,000 shares of the Company's common stock. Of these restricted stock units, one unit covering 60,000 shares of the Company's common stock was assigned no grant date fair value due to the Company's estimate of the probability that the performance goal would be achieved. The aggregate maximum fair value of the four performance-based restricted stock units on the grant date was \$1,480,000.
- (10) Amount includes performance-based and non-performance-based options and reflects the aggregate full grant date fair value of option awards granted during the year in accordance with FASB ASC Topic 718. The maximum fair value of the performance-based options at the grant date based on the Black-Scholes option-pricing model was \$4,074,924.
- (11) Represents reimbursement of Mr. Lichtinger's moving and relocation expenses.
- (12) Represents a sign-on bonus Mr. Webster received in connection with the start of his employment.
- (13) Represents the grant date fair value of (i) a time-vested restricted stock unit new hire award and (ii) the maximum number of shares underlying a performance-based restricted stock unit award that was canceled because the performance goal was not met.
- (14) Represents a one-time payment in respect of Mr. Webster's commuting costs in lieu of relocation expenses.
- (15) Represents amounts due and benefits provided in 2012 in connection with Mr. Prunty's termination, consisting of \$233,846 severance, \$37,288 accrued and unpaid vacation and \$13,626 continued health benefits. Additional information on total amounts payable in connection with Mr. Prunty's termination is located under the heading "Potential Payments on Termination or Change-in-control" below.
- (16) Represents the fair value of a performance-based restricted stock unit awarded by the Company and providing for the future delivery by the Company of 450,000 shares of common stock of OBI. This restricted stock unit was forfeited in connection with Mr. Prunty's termination in April 2012.
- (17) Mr. Hartman was hired in November 2010 and was not a named executive officer in 2010 or 2011. In connection with his resignation in February 2013, Mr. Hartman entered into a separation agreement providing for the acceleration or cancellation of certain equity awards as described in more detail under "Potential Payments Upon Termination or Change-in-control—Employment Agreement and Transition Arrangements."
- (18) Represents the grant date fair value of (i) a time-vested restricted stock unit award granted in connection with the marketing approval of DIFICID from the U.S. Food and Drug Administration and (ii) the maximum number of shares underlying a performance-based restricted stock unit award that was canceled because the performance goal was not met.
- (19) Dr. Amper was hired in January 2011.
- (20) Represents a sign-on bonus Dr. Amper received in connection with the start of her employment.
- (21) Represents legal service to review offer letter paid by the Company on behalf of Dr. Amper.
- (22) Mr. Papaz was hired in December 2010 and was not a named executive officer in 2010.
- (23) Represents amounts due and benefits provided in 2012 in connection with Mr. Papaz's termination, consisting of \$17,185 severance and \$23,935 accrued and unpaid vacation. Additional information on total amounts payable in connection with Mr. Papaz's termination is located under the heading "Potential Payments on Termination or Change-in-control" below.
- (24) Represents parking fees paid by the Company on behalf of Mr. Papaz.

# Employment and Change-in-control Arrangements

We have entered into offer letters with Drs. Amper and Gorbach and Mr. Webster. We also had offer letters with Messrs. Prunty and Papaz until their terminations in April 2012 and December 2012, respectively, an offer letter with Mr. Hartman until his resignation in February 2013 and an employment agreement with Mr. Lichtinger until his resignation in February 2013.

The offer letters and the employment agreement set forth the applicable executive's initial base salary and the terms of an initial stock option grant. Mr. Lichtinger's employment agreement also set forth the terms of four restricted stock unit and option awards, the vesting of which was subject to achievement of separate, specified performance goals. Mr. Webster's offer letter provides that his performance-based cash incentive for 2012 will not be prorated and sets forth the terms of the new-hire restricted stock unit grant and cash bonus described above under "Elements of Compensation, Long-Term Incentive Program" and "New Hire Bonus for Mr. Webster." Dr. Gorbach's offer letter sets forth the terms of certain performance-based cash and/or stock incentives, payment of which is subject to the achievement of specified performance goals. Each of our named executive officers is entitled to receive all customary and usual fringe benefits provided to our executives. Our named executive officers also have severance arrangements, which are described under the heading "Change-in-control and Severance Arrangements" above.

# Grants of Plan-based Awards

The following table presents information concerning grants of plan-based awards to each of our named executive officers during 2012.

		Under N	ted Future I Ion-equity I an Awards (	ncentive	Under	ted Future l Equity Inc an Awards (	entive	All Other Stock Awards: Number of	All Other Option Awards: Number of Securities Underlying	Exercise or Base Price of Option	Grant Date Fair Value of Stock and Option
Name	Grant Date	Threshold	Target	Maximum	Threshold	Target	Maximum	Stock or	Options	Awards	Awards
Pedro Lichtinger	Date	184,275	368,550	<u>(\$)</u> 552,825	(#)	(#)	(#)	Units (#)	(#)	(\$/Sh)	(\$)
redio Lichtinger	2/7/2012	104,273	306,330	332,623	50,400	67,200	84,000				1 124 040(2)
	2/7/2012				30,400	07,200	04,000		120,000(4)	13.51	1,134,840(3) 1,017,468
Stephen W. Webster	2///2012	73,000	146,000	219,000					120,000(4)	13.31	1,017,400
Stephen W. Webster	6/29/2012	75,000	110,000	217,000	9,000	12,000	15,000				231,900(3)
	6/29/2012				,,,,,,	12,000	15,000	25,000(5)			386,500
	6/29/2012							25,000(5)	100,000(5)	15.46	975,130
John D. Prunty	0,2,,2012	64,000	128,000	192,000					100,000(3)	15.40	775,150
	2/7/2012	,	,,	,	15,000	20,000	25,000				337,750(3)
	2/7/2012				•	,	,		35,000(4)	13.51	98,915
Kurt Hartman		62,000	124,000	186,000					, .(,		,
	2/7/2012				8,100	10,800	13,500			*	182,385(3)
	8/11/2012							3,500(6)	na n		53,060
	2/7/2012								18,750(4)	13.51	158,979
Linda E. Amper, Ph.D.		64,600	129,200	193,800							
	2/7/2012				8,100	10,800	13,500				182,385(3)
	2/7/2012								18,750(4)	13.51	158,979
Sherwood Gorbach, M.D.		66,000	132,000	198,000							
	8/10/2012							3,500(6)			53,060
	2/7/2012			200.000					24,320(4)	13.51	206,207
Gregory E. Papaz		63,600	127,200	190,800							
	2/7/2012				8,100	10,800	13,500				182,385(3)
	2/7/2012								18,750(4)	13.51	82,798

<sup>(1)</sup> Our Incentive Bonus Plan was our only non-equity incentive plan in 2012. The amounts shown in the "threshold," "target" and "maximum" columns reflect the payment levels under the Incentive Bonus Plan, determined by assuming that corporate and individual goals were achieved at a level of 50%, 100% and 150%, respectively.

Represents performance-based restricted stock units granted under our 2012 Equity Incentive Plan. Vesting of the performance-based restricted stock units was subject to achievement of at least 75% of a 2012 sales revenue target of \$107 million, and the amounts shown in the "threshold," "target" and "maximum" columns reflect the achievement levels under the awards, determined by assuming that the performance goal was achieved at a level of 75%, 100% and 125%, respectively. The threshold performance goal for these awards was not met, resulting in the cancelation of the awards.

Reflects grant date fair value of performance-based restricted stock units based on an assumed payout of the maximum number of shares.

Represents time-vested stock options granted under our 2012 Equity Incentive Plan.

Represents time-vested restricted stock units and stock options granted as new hire awards to Mr. Webster.

Represents non-performance-based restricted stock units granted by the Company in connection with the procurement of a New Technology Add-On Payment for DIFICID.

# Outstanding Equity Awards at Fiscal Year-End

The following table presents the outstanding equity awards held by each of our named executive officers as of December 31, 2012.

		(	Option Awards						
Name	Number of Securities Underlying Unexercised Options — Exercisable (#)	Number of Securities Underlying Unexercised Options — Unexercisable (#)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price (\$)	Option Expiration Date	Equity Incentive Plan Awards: Number of Earned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Earned Shares, Units or Other Rights That Have Not Vested (\$) (1)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested (\$) (1)
Pedro Lichtinger	129,166 31,666 36,666 27,791	70,834(2) 48,334(3) 43,334(3) 30,209(2) 120,000(2)		12.34 12.34 12.34 11.41 13.51	5/5/2020 5/5/2020 5/5/2020 1/26/2021 2/7/2022				
			80,000(4) 240,000(4)	12.34 12.34	5/5/2020 5/5/2020	13,125(5) 12,084(6) 10,834(6)	109,360	20,000(4	i) 181,000
Stephen W. Webster		100,000(2)		15.46	6/29/2022	25 020/7	226.250	60,000(4	
John D. Prunty Kurt Hartman	52,083	47,917(2) 18,750(2)		9.56 13.51	12/1/2020 2/7/2022	25,000(7) 3,500(7)			
Linda E. Amper, Ph.D.	47,916	52,084(2)		11.41 13.51	1/26/2021 2/7/2022	3,300(7)	31,073		
Sherwood Gorbach, M.D.	11,610(2) 1,298(2) 7,500(2) 100,000(8)	18,750(2)		1.08 1.08 6.90 6.59	2/2/2015 2/2/2015 1/4/2018 3/12/2018				
	9,166 8,750 11,250 19,166	834(2) 3,250(2) 8,750(2) 20,834(2) 24,320(2)	) 	13.68 11.85 9.03 11.41 13.51	4/6/2019 1/8/2020 9/15/2020 1/26/2021 2/7/2022	2.502	21.625		
Gregory E. Papaz	79,166(9) 9,764(10	)		11.42 13.51	12/11/2013 12/11/2013	3,500(7)	31,675		

Computed by multiplying the closing market price of our common stock on December 31, 2012 of \$9.05 by the number of restricted stock units set forth in this table. (1)

January 1 of the calendar year in which the applicable performance goal is achieved.

Represents time-vested restricted stock units granted by the Company in connection with the marketing approval of DIFICID from the U.S. Food and Drug Administration.

Represents time-vested restricted stock units that vest 1/3rd on each of the first, second and third anniversary of the grant date. Represents a time-vested stock option award pursuant to which 1/48th of the shares subject to the option vested monthly following the grant date.

Represents 31,250 stock options for which vesting was accelerated upon Mr. Papaz's termination and 47,916 stock options that were previously vested as of his termination.

Represents stock options for which vesting was accelerated upon Mr. Papaz's termination.

Represents a time-vested stock option award pursuant to which 1/4th of the shares subject to the option vest one year following vesting commencement date and 1/48th of the total shares subject to the option vest monthly thereafter.

Represents a performance-based stock option award where the performance goals were met in 2011 and pursuant to which 1/4th of the shares subject to the award vest upon the one-year anniversary of the achievement of the applicable performance goal and the remaining shares subject to the award vest in equal monthly installments over the following three-year period. Represents a performance-based restricted stock unit, pursuant to which the shares subject to the award vest in equal monthly installments over the two-year period beginning on

Represents a performance-based restricted stock unit award where the performance goals were met in 2011 and pursuant to which 1/4th of the shares subject to the award vest upon the one-year anniversary of the achievement of the applicable performance goal, and the remaining shares subject to the award vest in equal monthly installments over the following three-

# Option Exercises and Stock Vested During the 2012 Fiscal Year

The following table sets forth the number of stock option awards exercised and the value realized upon exercise during 2012 for our named executive officers, as well as the number of stock awards vested and the value realized upon vesting.

# Option Exercises and Stock Vested Table for Fiscal Year 2012

	Option	Awards	Stock Awards				
Name	Number of Shares Acquired on Exercise (#)	Value Realized on Exercise (\$)(1)	Number of Shares Acquired on Vesting (#)	Value Realized on Vesting (\$)(2)			
Pedro Lichtinger			24,957	347,776			
John D. Prunty	249,452	2,090,361	<u> </u>				

<sup>(1)</sup> Based on the difference between the price of the market price of our common stock at the time of exercise and the exercise prices for the stock options.

(2) Based on the closing market price of our common stock on the applicable vesting dates.

#### **Pension Benefits**

None of our named executive officers participate in or have account balances in qualified or non-qualified defined benefit plans sponsored by us.

# Non-qualified Deferred Compensation

None of our named executive officers participate in or have account balances in non-qualified defined contribution plans or other deferred compensation plans maintained by us. The Committee, which is comprised solely of "outside directors" as defined for purposes of Section 162(m) of the Internal Revenue Code, may elect to provide our officers and other employees with non-qualified defined contribution or deferred compensation benefits if the Committee determines that doing so is in our best interests.

# Potential Payments Upon Termination or Change-in-control

#### Severance Plan

Under the Severance Plan, which was originally adopted in October 2008, our named executive officers may receive severance benefits upon a covered termination, including involuntary termination without "cause" or a "constructive termination," in each case as defined in the Severance Plan. The benefits may include continuation of base salary payments, bonus payments, group health benefits and acceleration of stock award vesting. The level of benefits provided under the plan depends upon an eligible employee's position and years of service, and whether the covered termination is related to a "change of control" as defined in the Severance Plan. Effective February 26, 2013, the Severance Plan was amended to provide that employees at the level of "director" or below will receive continuation of base salary continuation and group health benefits for a minimum of three months if they experience a covered termination that occurs upon, or within twelve months following, a change of control and that employees may be eligible for participation in the Severance Plan without regard to the length of time they have been employed by the Company.

If our Chief Executive Officer, any of our Company officers or any of our Senior Vice Presidents or Vice Presidents experience a covered termination that occurs either prior to, or more than 12 months following, a change of control, they will be entitled to 24, 15 and 12 months of continued base salary payments, respectively, 24, 15 and 12 months of continued group health benefits, respectively, and accelerated vesting of all then-unvested and outstanding non-performance-based equity awards equal to 24, 15 and 12 months, respectively.

If our Chief Executive Officer, any of our Company officers or any of our Senior Vice Presidents or Vice Presidents experience a covered termination that occurs upon or within 12 months following a change of control, they will be entitled to 24, 18 and 12 months of continued base salary payments, respectively, 24, 18 and 12 months of continued group health benefits, respectively and 100% immediate accelerated vesting of all non-performance-based equity awards. Any performance-based equity awards held by our Chief Executive Officer, any of our Company officers or any of our Senior Vice Presidents or Vice Presidents as of the date of a covered termination that occurs upon or within 12 months following a change of control are subject to 100% immediate accelerated vesting as if each of their target goals had been achieved to the maximum extent possible. In addition, our Chief Executive Officer, any of our Company officers or any of our Senior Vice Presidents or Vice Presidents will be paid 200%, 150% and 100%, respectively, of their eligible bonus in effect at the time of the covered termination that occurs upon or within 12 months following a change of control.

Termination of employment for "cause" means a termination resulting from the occurrence of any of the following events that has a material negative impact on our business or reputation: (i) the employee's attempted commission of, or participation in, a fraud or act of dishonesty against us; (ii) the employee's intentional, material violation of any contract or agreement between the employee and us or of any statutory duty owed us; (iii) the employee's unauthorized use or disclosure of our confidential information or trade secrets; (iv) an employee's intentional refusal or intentional failure to act in accordance with any lawful and proper direction or order of his or her superiors; (v) an employee's habitual neglect of the duties of employment; (vi) an employee's indictment, charge or conviction of a felony, or any crime involving moral turpitude or participation in any act of theft or dishonesty; or (vii) the employee's gross misconduct. "Change of control" means any of the following events: (i) a sale, lease or disposition of all or substantially all of our assets; or (ii) a merger or consolidation (in a single transaction or series or related transactions) of us with or into any other corporation or corporations or other entity, or any other corporate reorganizations, where our stockholders immediately prior to such event do not retain more than 50% of the voting power and interest in the successor entity (excluding any transactions if the primary purpose of the transaction is to obtain financing from new or existing investors). Our Board of Directors shall have the right to determine whether a change of control has occurred in accordance with the foregoing definition, and its determination shall be final, binding and conclusive on all persons. "Constructive termination" means the occurrence of one or more of the following events, provided that the eligible employee has first provided written notice to us within 90 days of the first such occurrence of such condition specifying the event(s) constituting constructive termination and specifying that the eligible employee intends to terminate employment not earlier than 30 days after providing such notice, and we (or surviving corporation) have not cured such event(s) within 30 days (or such longer period as may be specified by the eligible employee in such notice) after such written notice is received by us which we refer to as the cure period and the eligible employee resigns within 30 days following the end of the cure period: (i) a material diminution in the employee's authority, duties or responsibilities; (ii) relocation of the employee's principal work location that materially adversely affects the employee's commute (including, without limitation, a one-way increase in the distance of the employee's commute of 15 miles or a one-way increase in the time of the employee's commute of more than 30 minutes); or (iii) a material reduction in the employee's annual base compensation other than a reduction applicable to all of our senior executives.

In order to receive any benefits under the Severance Plan, individuals must sign a general release and waiver of all claims against the Company, remain on the job until the date of termination and return all of the Company's property. In addition, severance benefits will terminate immediately if during the severance period the individual violates any material proprietary information, non-disparagement, confidentiality or non-solicitation obligation to us. Any severance benefits that may be provided to any individual employed by us under the Severance Plan shall be automatically reduced by any severance benefits provided to such employee pursuant to any employment agreement they may have with us, unless otherwise specifically provided under the terms of such agreement.

# Incentive Plans

2006 Equity Incentive Plan. The 2006 Equity Incentive Plan was replaced effective May 2012 by our 2012 Equity Incentive Plan, which is a successor to and continuation of our 2006 Equity Incentive Plan and is described further below. Following stockholder approval of the 2012 Equity Incentive Plan in May 2012, no additional stock awards were granted under our 2006 Equity Incentive Plan, although all outstanding stock awards granted under the 2006 Equity Incentive Plan continue to be subject to the terms and conditions as set forth in the agreements evidencing such stock awards and the terms of the 2006 Equity Incentive Plan. Our 2006 Equity Incentive Plan provides that in the event of a "change-in-control," the successor corporation or its parent or subsidiary will assume or substitute an equivalent award for each outstanding award. The definition of a "change-in-control" for the purposes of the 2006 Equity Incentive Plan includes the events described above under the definition of "change of control" in the Severance Plan, as well as: (i) a change in the composition of the Board of Directors occurring within a two-year period, as a result of which fewer than a majority of the directors are directors who either were directors as of the effective date of the 2006 Equity Incentive Plan ("Incumbent Directors"), or were elected, or nominated for election, to the Board of Directors with the affirmative votes of at least a majority of the Incumbent Directors at the time of such election or nomination (but will not include an individual whose election or nomination is in connection with an actual or threatened proxy contest relating to the election of directors to the Company); or (ii) any "person" (as such term is used in Sections 13(d) and 14(d) of the Exchange Act) becomes the "beneficial owner" (as defined in Rule 13d-3 of the Exchange Act), directly or indirectly, of securities of the Company representing fifty percent (50%) or more of the total voting power represented by the Company's then outstanding voting securities. If there is no assumption or substitution of outstanding awards, the awards will fully vest, all restrictions shall lapse and the awards will become fully exercisable. The administrator will provide notice to the recipient that he or she has the right to exercise any option and stock appreciation right as to all of the shares subject to the award, all restrictions on restricted stock will lapse, and all performance goals or other vesting requirements for any performance shares and units will be deemed achieved and all other terms and conditions met. Any option or stock appreciation right will terminate upon the expiration of the period of time the administrator provides in the notice. In the event the service of an outside director is terminated on or following a change-in-control, other than pursuant to a voluntary resignation, any of his or her options and stock appreciation rights will fully vest and become immediately exercisable, all restrictions on restricted stock will lapse and all performance goals or other vesting requirements for any performance shares and units will be deemed achieved and all other terms and conditions met.

2012 Equity Incentive Plan. Our Board of Directors adopted our 2012 Equity Incentive Plan in February 2012 and subsequently amended it in March 2012. Our stockholders approved the plan in May 2012. The 2012 Equity Incentive Plan is the successor to, and continuation, of our 2006 Equity Incentive Plan. Our 2012 Equity Incentive Plan provides for the grant of incentive stock options, within the meaning of Section 422 of the Internal Revenue Code, to our 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 our employees, directors and consultants and any parent and subsidiary corporations' employees and consultants. Under the 2012 Equity Incentive Plan, a stock award may be subject to additional acceleration of vesting and exercisability upon or after a "change-in-control" as may be provided in the stock award agreement or other written agreement with the participant, but in the absence of such provision, no such acceleration will occur. The definition of a "change-in-control" for the purposes of the 2012 Equity Incentive Plan is substantially similar to the definition described for the purposes of the 2006 Equity Incentive Plan.

Incentive Bonus Plan. In February 2012, as described above, our Committee adopted the Incentive Bonus Plan. Under this plan, in the event of a change-in-control, all participants will receive a prorated portion of the annual bonus for the year in which the change-in-control occurs, calculated on the basis of each participant's target award for that year and on the assumption that all performance goals have been or will be achieved at 100%.

# **Employment Agreement and Transition Arrangements**

Employment Agreement with Mr. Lichtinger. In May 2010, we entered into an offer letter with Mr. Lichtinger setting forth the terms of Mr. Lichtinger's employment as President and Chief Executive Officer. In connection with his appointment as President and Chief Executive Officer, we granted Mr. Lichtinger performance-based restricted stock units covering an aggregate of 120,000 shares of our common stock and performance-based stock options to purchase an aggregate of 480,000 shares of our common stock, all of which were scheduled to commence vesting upon the satisfaction of specified performance objectives. Pursuant to the employment agreement, if Mr. Lichtinger had experienced a covered termination (as defined in the Severance Plan) within 12 months following a change of control (as defined in the Severance Plan), the vesting of these performance-based restricted stock units and stock options which had not begun to vest would have been accelerated with respect to 50% (in the case of a covered termination occurring on or prior to the first anniversary of Mr. Lichtinger's start date), 60% (in the case of a covered termination occurring after the second anniversary but on or prior to the third anniversary of Mr. Lichtinger's start date), 85% (in the event of a covered termination occurring after the third anniversary but on or prior to the fourth anniversary of Mr. Lichtinger's start date) of these awards in lieu of the acceleration of these performance-based equity awards that would have been provided for under the Severance Plan.

The initial term of Mr. Lichtinger's employment agreement was three years. Pursuant to the treatment of Mr. Lichtinger's resignation as a termination of employment without cause and without prior notice, Mr. Lichtinger was entitled to receive a lump-sum cash payment equal to the sum of Mr. Lichtinger's then-current base salary plus the annual bonus paid to Mr. Lichtinger for the previous year, prorated to his remaining employment term subject to meeting the eligibility requirements described above. Any severance benefits provided to Mr. Lichtinger under the Severance Plan will be automatically reduced by any severance benefits provided under Mr. Lichtinger's employment agreement.

Transition Arrangements. In connection with his resignation, Mr. Lichtinger and the Company entered into a separation agreement, effective as of April 1, 2013, pursuant to which Mr. Lichtinger is eligible receive, subject to continued compliance with certain terms and conditions: (i) an amount equal to twenty-four months of his base salary and a cash bonus, in each case less applicable tax withholding; (ii) twenty-four months of continued group health benefits; and (iii) acceleration of 30,500 unvested restricted stock units and 230,292 unvested stock options with a weighted average exercise price of \$12.53.

In connection with his resignation, Mr. Hartman and the Company entered into a separation agreement, effective as of March 2, 2013, pursuant to which Mr. Hartman is eligible to receive, subject to continued compliance with certain terms and conditions: (i) an amount equal to fifteen months of his base salary and a cash bonus, in each case less applicable tax withholding; (ii) fifteen months of continued group health benefits; and (iii) acceleration of 1,167 unvested restricted stock units and 37,109 unvested stock options with a weighted average exercise price of \$10.18.

The following table provides information as to the amounts potentially payable upon termination of the named executive officers or in the event of a change-in-control of the Company as discussed above and assuming a triggering event occurred on December 31, 2012. With respect to Messrs. Prunty and Papaz, we have included only the amounts payable in connection with their actual terminations because they were no longer employed by us on December 31, 2012. The amounts paid or benefits payable in 2012 to Messrs. Prunty and Papaz in connection with their terminations are set forth in the "Summary Compensation Table" and the "Option Exercises and Stock Vested Table for 2012" and the related discussions above.

	Termination without Cause or Resignation for Good Reason (\$)	Termination without Cause or Resignation for Good Reason within 12 months of Change-in-control (\$)
Name and Benefit	Ioi Good Reason (4)	Change-in-control (4)
Pedro Lichtinger	1,134,000	1,134,000
Salary	1,134,000	680,400
Bonus	133,481	326,189
Accelerated vesting of stock awards (1)	-	49,923
Group health insurance	49,923	49,923
Stephen W. Webster	456.250	547.500
Salary	456,250	547,500
Bonus	<del>-</del>	219,000
Accelerated vesting of stock awards (1)	75,423	226,250
Group health insurance	31,202	37,442
John D. Prunty		
Salary	400,000	
Bonus	_	
Accelerated vesting of stock awards (1)	121,098	
Group health insurance	25,777	
Kurt Hartman		
Salary	387,500	465,000
Bonus	<del>-</del>	186,000
Accelerated vesting of stock awards (1)	10,561	31,675
Group health insurance	31,202	37,422
Linda E. Amper, Ph.D.	,-	,
Salary	403,750	484,500
Bonus		193,800
Accelerated vesting of stock awards (1)	<u> </u>	
· · · · · · · · · · · · · · · · · · ·	10,011	12,014
Group health insurance	10,011	12,014
Sherwood Gorbach, M.D.	412,500	495,000
Salary	412,500	198,000
Bonus	10.686	31,850
Accelerated vesting of stock awards (1)	10,686	
Group health insurance	21,660	25,973
Gregory E. Papaz	400 0	
Salary	403,956	
Bonus	+	
Accelerated vesting of stock awards (1)	<del> </del>	
Group health insurance	9,109	

<sup>(1)</sup> Represents the value of accelerated restricted stock units (computed by multiplying the closing market price of our common stock on December 31, 2012 of \$9.05, times the number of each restricted stock unit vested as a result of the termination), plus the value of accelerated options (computed by multiplying the difference between \$9.05 and the exercise price of each stock option vested as a result of the termination by the number of accelerated stock options with an exercise price less than \$9.05).

#### **Director Compensation**

The following table sets forth summary information concerning compensation paid or accrued for services rendered to us in all capacities to the non-employee members of our Board of Directors for the fiscal year ended December 31, 2012.

Name (1)	Fees Earned or Paid in Cash (\$)	Stock Awards (\$) (2)	Total (\$)
Anthony E. Altig	73,333	98,550	171,883
Mark Auerbach	80,000	98,550	178,550
Joseph Y. Chang, Ph.D.	60,000	98,550	158,550
Michael N. Chang, Ph.D.	97,500	61,200	158,700
Peter E. Grebow, Ph.D.	61,250	98,550	159,800
Henry A. McKinnell, Ph.D. (Chairman as of April 2012)	85,000	210,600	295,600
Stephen Newman	30,000		30,000
Robert L. Zerbe, M.D.	60,000	98,550	158,550

(1) Information regarding Mr. Lichtinger's compensation during 2012 is set forth the Summary Compensation Table above.

All of our directors are eligible to participate in our 2012 Equity Incentive Plan and our employee directors are eligible to participate in our employee stock purchase plan. For a more detailed description of these plans, see "— Employee Benefit Plans."

Each director who is not an employee of the Company receives an annual cash retainer fee for service as a member of the Board of Directors. In May 2012, the Committee approved an increase to this annual retainer to \$60,000 for members of the Board and \$90,000 for the Chairman of the Board, as well as an increase to the additional annual retainer paid to the head of each of the Committee and the Audit Committee to \$20,000. The Committee eliminated the annual retainer paid to non-chair members of the Board's standing committees.

Each director, upon election or appointment to the Board of Directors, receives a grant of a stock option to purchase up to 20,000 shares of common stock, which vests monthly over forty-eight months. Each director also receives an annual restricted stock unit grant and, in May 2012, the Committee approved an increase to this grant to 10,000 restricted stock units for the Chairman of the Board of Directors and 7,500 restricted stock units for the other directors. The restricted stock units vest on January 1 of the year following the award date. We have reimbursed, and will continue to reimburse, our non-employee directors for their reasonable expenses incurred in attending meetings of the Board of Directors and committees of the Board of Directors.

#### **Stock Ownership Guidelines**

In February 2012, we adopted stock ownership guidelines applicable to our executive officers and directors. The purpose of stock ownership guidelines is to align the interests of our directors and executive officers with the interests of our stockholders and to further promote our commitment to sound corporate governance. The guidelines are intended to require the covered individuals to accumulate a substantive interest in our common stock prior to the later of: (i) December 31, 2017; or (ii) December 31 of the fifth year following the covered individual becoming subject to the guidelines and to maintain that interest thereafter. Our stock ownership guidelines provide that members of our Board of Directors should hold common stock of the Company with a value equal to three times his annual retainer, our Chief Executive Officer should hold common stock of the Company with a value equal to three times his or her annual base salary and our other named executive officers should hold common stock of the Company with a value equal to one times his or her annual base salary. Shares of Company common stock that count toward these guidelines include shares owned outright by the individual or his or her immediate family members and vested shares of stock granted under the Company's equity incentive plans, including shares purchased and retained under the employee stock purchase plan, but excluding vested shares of stock subject to an unexercised stock option.

<sup>(2)</sup> Amounts shown reflect aggregate full grant date fair value of option awards granted during the year in accordance with FASB ASC Topic 718. Pursuant to FASB ASC Topic 718, the amounts shown here exclude the impact of estimated forfeitures related to service-based vesting conditions. For additional information, on the valuation assumptions underlying the value of these options, see Part II, Item 8 "Financial Statements and Supplementary Date" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2012 in the Notes to Consolidated Financial Statements, Note 8, "Stockholders Equity."

#### **Indemnification and Insurance**

We have entered into indemnification agreements with each of our executive officers and directors. These indemnification agreements require us to indemnify these individuals to the fullest extent permitted by Delaware law. In addition, we have purchased directors' and officers' liability insurance policies that insure our directors and officers against the cost of defense, settlement or payment of a judgment in some circumstances.

# SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth the beneficial ownership information of our common stock by:

- each person known to us to be the beneficial owner of more than 5% of our common stock;
- each named executive officer;
- each of our directors; and
- all of our executive officers and directors as a group.

We have based our calculation of the percentage of beneficial ownership of 47,900,542 shares of common stock outstanding on March 11, 2013.

Each individual or entity shown in the table has furnished information with respect to beneficial ownership. The information with respect to our executive officers and directors is as of March 11, 2013 unless otherwise noted. The information with respect to certain significant stockholders is based on filings by the beneficial owners with the SEC pursuant to Section 13(d) and 13(g) of the Exchange Act. We have determined beneficial ownership in accordance with the SEC's rules. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, these rules include shares of common stock issuable pursuant to the exercise of stock options or warrants that are either immediately exercisable or will be exercisable on or before May 10, 2013, which is 60 days after March 11, 2013. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Except as otherwise noted below, the address for each person or entity listed in the table is c/o Optimer Pharmaceuticals, Inc., 101 Hudson Street, Suite 3501, Jersey City, NJ 07302.

Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned		
5% Stockholders (1):				
FMR LLC (2)				
82 Devonshire Street				
Boston, MA 02109	5,389,095	11.3%		
BlackRock, Inc. (3)				
40 East 52nd Street				
New York, NY 10022	5,291,761	11.0%		
T. Rowe Price Associates, Inc. (4)				
100 E. Pratt Street				
Baltimore, MD 21202	5,211,459	10.9%		
Wellington Management Company, LLP (5)				
280 Congress Street				
Boston, MA 02210	3,300,331	6.9%		
The Vanguard Group (6)				
100 Vanguard Blvd.				
Malvern, PA 19355	2,517,642	5.3%		
Directors and Named Executive Officers:				
Henry A. McKinnell (7)	36,666	*		
Anthony E. Altig (8)	50,000	*		
Mark Auerbach (9)	40,961	*		
Joseph Y. Chang (10)	97,498	*		
Michael N. Chang (11)	1,658,383	3.4%		
Peter E. Grebow (12)	50,000	*		
Stephen M. Newman	0	*		
Robert L. Zerbe (13)	43,541			
Linda E. Amper (14)	62,108	*		
Sherwood L. Gorbach (15)	222,976	*		
Stephen W. Webster	0	*		
Kurt M. Hartman (16)	97,129	*		
Pedro Lichtinger (17)	601,336	1.2%		
Gregory E. Papaz (18)	91,522	*		
John D. Prunty (19)	12,985	*		
All directors and executive officers as a group (12 persons) (20)	2,272,133	4.7%		

<sup>\*</sup> Less than 1%.

<sup>(1)</sup> We have been informed that funds or affiliates managed by Ruentex Group own over 5% of our common stock, but we have been unable to verify their ownership percentage.

<sup>(2)</sup> A report on Schedule 13G filed with the SEC on February 14, 2013 indicates that FMR LLC had sole voting power with respect to 141,000 shares of common stock and had sole power to dispose or to direct the disposition of 5,389,095 shares of common stock. Various persons had the right to receive or the power to direct the receipt of dividends from, or the proceeds from the sale of the common stock of the Company. No one person's interest in the common stock was more than five percent of the total outstanding common stock of the Company.

<sup>(3)</sup> A report on Schedule 13G filed with the SEC on March 11, 2013 indicates that BlackRock Inc. had sole voting power and had sole power to dispose or to direct the disposition of 5,291,761 shares of common stock. Various persons had the right to receive or the power to direct the receipt of dividends from, or the proceeds from the sale of the common stock of the Company. No one person's interest in the common stock was more than five percent of the total outstanding common stock of the Company.

<sup>(4)</sup> A report on Schedule 13G filed with the SEC on February 11, 2013 indicates that T. Rowe Price Associates, Inc. had sole voting power with respect to 577,079 shares of common stock and had sole dispositive power of 5,211,459 shares of common stock. T. Rowe Price Associates, Inc. does not serve as custodian of the assets of any of its clients; accordingly, in each instance only the client or the client's custodian or trustee bank had the right to receive dividends paid with respect to, and proceeds from the sale of, such securities. The ultimate power to direct the receipt of dividends paid with respect to, and the proceeds from the sale of such securities was vested in the individual and institutional clients for whom T. Rowe Price Associates, Inc. served as investment adviser. Any and all discretionary authority which had been delegated to T. Rowe Price Associates, Inc. may have been revoked in whole or in part at any time. No such client's interest in the common stock was more than five percent of the total outstanding common stock of the Company.

- (5) A report on Schedule 13G filed with the SEC on February 14, 2013 indicates that Wellington Management Company, LLP had shared voting power with respect to 2,119,534 shares of common stock and had shared dispositive power of 3,300,331 shares of common stock. These securities were owned of record by clients of Wellington Management Company, LLP, in its capacity as investment adviser. Those clients had the right to receive, or the power to direct the receipt of, dividends from, or the proceeds from the sale of, such securities. To the knowledge of Wellington Management Company, LLP, no such client had such right or power with respect to more than five percent of the total outstanding common stock of the Company.
- (6) A report on Schedule 13G filed with the SEC on February 13, 2013 indicates that The Vanguard Group had sole voting power with respect to 60,393 shares of common stock, had sole dispositive power of 2,458,479 shares of common stock and had shared dispositive power of 59,163 shares of common stock. Vanguard Fiduciary Trust Company, a wholly-owned subsidiary of The Vanguard Group, Inc., was the beneficial owner of 59,163 shares of the common stock outstanding of the Company as a result of its serving as investment manager of collective trust accounts. Vanguard Investments Australia, Ltd., a wholly-owned subsidiary of The Vanguard Group, Inc., was the beneficial owner of 1,200 shares of the common stock outstanding of the Company as a result of its serving as investment manager of Australian investment offerings.
- Includes (i) 10,000 shares of common stock held by Dr. McKinnell; (ii) 21,666 shares of common stock that Dr. McKinnell has the right to acquire from us within 60 days of March 11, 2013 pursuant to the exercise of stock options; and (iii) 5,000 shares underlying a restricted stock unit that will vest upon Dr. McKinnell's separation from the Company.
- (8) Includes (i) 5,000 shares of common stock held by Mr. Altig; (ii) 40,000 shares of common stock that Mr. Altig has the right to acquire from us within 60 days of March 11, 2013 pursuant to the exercise of stock options; and (iii) 5,000 shares underlying a restricted stock unit that will vest upon Mr. Altig's separation from the Company.
- (9) Includes (i) 7,500 shares of common stock held by Mr. Auerbach; and (ii) 33,461 shares of common stock that Mr. Auerbach has the right to acquire from us within 60 days of March 11, 2013 pursuant to the exercise of stock options.
- Includes (i) 7,500 shares of common stock held by Dr. Joseph Chang; (ii) 43,844 shares of common stock that Dr. Joseph Chang has the right to acquire from us within 60 days of March 11, 2013 pursuant to the exercise of stock options; and (iii) 46,154 shares of common stock held by his wife, Wan Ping Chang.
- Includes (i) 483,256 shares of common stock held by Dr. Michael Chang; (ii) 692,366 shares of common stock that Dr. Michael Chang has the right to acquire from us within 60 days of March 11, 2013 pursuant to the exercise of stock options; (iii) 338,146 shares of common stock owned by his wife, Tessie M. Che, our former Chief Operating Officer; and (iv) 144,615 shares that Ms. Che has the right to acquire from us within 60 days of March 11, 2013 pursuant to the exercise of stock options.
- (12) Includes (i) 45,000 shares of common stock that Dr. Grebow has the right to acquire from us within 60 days of March 11, 2013 pursuant to the exercise of stock options; and (ii) 5,000 shares underlying a restricted stock unit that will vest upon Dr. Grebow's separation from the Company.
- Includes (i) 38,541 shares of common stock that Dr. Zerbe has the right to acquire from us within 60 days of March 11, 2013 pursuant to the exercise of stock options; and (ii) 5,000 shares underlying a restricted stock unit that will vest upon Dr. Zerbe's separation from the Company.
- (14) Includes 62,108 shares of common stock that Dr. Amper has the right to acquire from us within 60 days of March 11, 2013 pursuant to the exercise of stock options.
- (15) Includes (i) 38,719 shares of common stock held by Dr. Gorbach; and (ii) 184,257 shares of common stock that Dr. Gorbach has the right to acquire from us within 60 days of March 11, 2013 pursuant to the exercise of stock options.
- Includes (i) 1,167 shares of common stock held by Mr. Hartman; and (ii) 95,962 shares of common stock that Mr. Hartman has the right to acquire from us within 60 days of March 11, 2013 pursuant to the exercise of stock options.
- Includes (i) 69,503 shares of common stock held by Mr. Lichtinger; (ii) 501,333 shares of common stock that Mr. Lichtinger has the right to acquire from us within 60 days of March 11, 2013 pursuant to the exercise of stock options; and (iii) 30,500 shares underlying a restricted stock unit that will vest within 60 days of March 11, 2013.
- (18) Includes (i) 2,592 shares of common stock as reported to the Company by Mr. Papaz as of March 29, 2013; and (ii) 88,930 shares of common stock that Mr. Papaz has the right to acquire from us within 60 days of March 11, 2013 pursuant to the exercise of stock options.
- (19) Includes 11,985 shares of common stock as reported to the Company by Mr. Prunty as of March 27, 2013.
- Includes an aggregate of (i) 1,171,243 shares of common stock that current executive officers and directors have the right to acquire from us within 60 days of March 11, 2013 pursuant to the exercise of stock options; and (ii) 20,000 shares underlying restricted stock units that will vest within 60 days of March 11, 2013 or upon certain individuals' separation from the Company as indicated in the footnotes above.

# Securities Authorized for Issuance under Equity Compensation Plans

The following table sets forth certain information with respect to all of our equity compensation plans in effect as of December 31, 2012:

#### **Equity Compensation Plan Information**

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Price	d-Average Exercise of Outstanding arrants and Rights (1) (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column(a)) (c)		
Equity compensation plans approved by security holders (2)	4,627,215	\$	11.24	4,744,205		
Equity compensation plans not approved by security holders (3)	2,039,642	·	12.67	280,672		
Total	6,666,857	\$	11.70	5,024,877		

<sup>(1)</sup> The weighted-average exercise price does not take into account 372,283 shares subject to outstanding restricted stock units that have no exercise price.

In November 1998, the Company adopted the 1998 Stock Plan. The Company terminated and ceased granting options under the 1998 Stock Plan upon the closing of the Company's initial public offering in February 2007. As of December 31, 2012, there were 235,780 shares of our common stock reserved for issuance pursuant to options outstanding under the 1998 Stock Plan.

The 2006 Equity Incentive Plan was originally adopted by our Board of Directors in December 2006 and was approved by our stockholders in January 2007. The 2006 Equity Incentive Plan was succeeded by the 2012 Equity Incentive Plan, which became effective upon approval by our stockholders on May 9, 2012. After May 9, 2012, no additional stock awards were awarded under the 2006 Equity Incentive Plan. However, all outstanding stock awards granted under the 2006 Equity Incentive Plan. As of December 31, 2012, there were 3,710,482 shares of our common stock reserved for issuance pursuant to options outstanding and 278,543 shares reserved for issuance upon the vesting of outstanding restricted stock units under the 2006 Equity Incentive Plan.

The 2012 Equity Incentive Plan is a continuation of the 2006 Equity Incentive Plan. Upon its adoption, the maximum number of shares of the Company's common stock issuable under the 2012 Equity Incentive Plan was 11,289,455, which consisted of (a) 3,400,000 new shares and (b) the number of unallocated shares remaining available for grant of new awards under the 2006 Equity Incentive Plan as of May 9, 2012. As of December 31, 2012, there were 320,750 shares of our common stock reserved for issuance pursuant to options outstanding and 81,660 shares reserved for issuance upon the vesting of outstanding restricted stock units under the 2012 Equity Incentive Plan.

The employee stock purchase plan was originally adopted by our Board of Directors in December 2006 and was approved by our stockholders in January 2007. A total of 200,000 shares of our common stock were initially made available for sale under the employee stock purchase plan. In addition, the employee stock purchase plan provides for annual increases in the number of shares available for issuance under the employee stock purchase plan on the first day of each fiscal year, beginning with our 2008 fiscal year, equal to the lesser of (i) 3% of the outstanding shares of our 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 Board of Directors. Pursuant to this provision, 300,000 additional shares of our common stock were reserved for issuance under the employee stock purchase plan on January 1, 2008 and on January 1, 2012. The Board of Directors determined to reserve zero additional shares under the employee stock purchase plan on each of January 1, 2009, 2010 and 2011. The employee stock purchase plan allows for qualified employees to purchase shares of our common stock at a price equal to the lower of 85% of the closing price at the beginning of the offering period or 85% of the closing price at the end of each purchase period. The employee stock purchase plan is implemented by one offering period during each six-month period; provided, however, our Board of Directors may alter the duration of an offering period without stockholder approval. Employees may authorize up to 10% of their compensation for the purchase of stock under the employee stock purchase plan, provided that an employee may not accrue the right to purchase stock at a rate of more than \$25,000 of the fair market value of our common stock for each calendar year in which the purchase right is outstanding and that an employee may not purchase more than 2,500 shares of common stock during any offering period. As of December 31, 2012, there were 409,806 sha

(3) In March and June 2011, our Board of Directors amended the 2006 Equity Incentive Plan to reserve an additional 1,750,000 and 1,000,000 shares, respectively, of our common stock to be issued exclusively as employment inducements pursuant to Rule 5635(c)(4) of the Nasdaq Listing Rules.

In November 2012, our Board of Directors amended the 2012 Equity Incentive Plan to reserve an additional 300,000 shares of our common stock to be issued exclusively as employment inducements pursuant to Rule 5635(c)(4) of the Nasdaq Listing Rules.

<sup>(2)</sup> Represents shares of our common stock issuable under the 2012 Equity Incentive Plan, the 2006 Equity Incentive Plan, the employee stock purchase plan and the 1998 Stock Plan, except with respect to certain shares issuable under our 2012 Equity Incentive Plan and 2006 Equity Incentive Plan as described in Footnote 3.

#### **PROPOSAL 2**

# RATIFICATION OF SELECTION OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Audit Committee of the Board of Directors has selected Ernst & Young LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2013 and has further directed that management submit the selection of the independent registered public accounting firm for ratification by the stockholders at the Annual Meeting. Ernst & Young LLP has audited the Company's financial statements since its inception in November 1998. Representatives of Ernst & Young LLP are expected to be present at the Annual Meeting. They will have an opportunity to make a statement if they so desire and will be available to respond to appropriate questions.

Neither the Company's bylaws nor other governing documents or law require stockholder ratification of the selection of Ernst & Young LLP as the Company's independent registered public accounting firm. However, our Audit Committee is submitting the selection of Ernst & Young LLP to the stockholders for ratification as a matter of good corporate practice. If the stockholders fail to ratify the selection, our Audit Committee will reconsider whether or not to retain that firm as our independent registered public accounting firm. Even if the selection is ratified, our Audit Committee, in its discretion, may direct the appointment of a different independent registered public accounting firm at any time during the year if it determines that such a change would be in the best interests of the Company and our stockholders.

The affirmative vote of the holders of a majority of the shares present in person or represented by proxy and entitled to vote at the Annual Meeting will be required to ratify the selection of Ernst & Young LLP. Abstentions will be counted toward the tabulation of votes cast on this proposal and will have the same effect as negative votes.

# **Principal Accountant Fees and Services**

The following table represents aggregate fees for services provided to the Company for the fiscal years ended December 31, 2012 and 2011, by Ernst & Young LLP, the Company's principal accountant.

	Fiscal Year Ended December 31, (in thousands)			
		2012		2011
Audit Fees (1)	\$	1,230	\$	715
Audit-related Fees (2)		95		125
Tax Fees (3)		960		380
All Other Fees		<del></del>		
Total Fees	\$	2,285	\$	1,220

<sup>(1)</sup> Audit Fees consist of fees billed for professional services, including out-of-pocket expenses. The amounts presented relate to the audit of our annual financial statements, review of our registration statements on Form S-8 and S-3, our prospectus supplements and the related services that are normally provided in connection with statutory and regulatory filings or engagements.

(2) Audit-related Fees consist of fees for professional services performed for assurance and related services that are reasonably related to the performance of the audit of our annual financial statements and are not reported as Audit Fees. The amounts presented are related to consultation on matters such as our internal controls review, the impact of final or proposed regulatory guidance and the accounting treatment or disclosure of transactions or events.

(3) Tax fees consist of fees for tax compliance and consultations.

All 2012 and 2011 fees described above were pre-approved by the Audit Committee. The Audit Committee has considered whether the provision of non-audit services is compatible with maintaining the independence of Ernst & Young LLP and has concluded that the provision of such services is compatible with maintaining the independence of our auditors.

# **Pre-approval Policies and Procedures**

The Audit Committee has adopted a policy and procedures for the pre-approval of audit and non-audit services rendered by our independent registered public accounting firm, Ernst & Young LLP. The policy generally pre-approves specified services in the defined categories of audit services, and audit-related services up to specified amounts. Pre-approval may also be given as part of the Audit Committee's approval of the scope of the engagement of the independent registered public accounting firm or on an individual explicit case-by-case basis before the independent registered public accounting firm is engaged to provide each service. The pre-approval of services may be delegated to one or more of the Audit Committee's members, but the decision must be reported to the full Audit Committee at its next scheduled meeting.

The Audit Committee has determined that the rendering of the services other than audit services by Ernst & Young LLP is compatible with maintaining the registered public accounting firm's independence.

THE BOARD OF DIRECTORS RECOMMENDS A VOTE IN FAVOR OF PROPOSAL 2.

## PROPOSAL 3

# ADVISORY VOTE ON EXECUTIVE COMPENSATION

Under the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Dodd-Frank Act"), and Section 14A of the Exchange Act, our stockholders are entitled to vote to approve, on an advisory basis, the compensation of our named executive officers, as disclosed in this proxy statement. This vote is not intended to address any specific item of compensation, but rather the overall compensation of our named executive officers and the philosophy, policies and practices described in this proxy statement. Pursuant to the Dodd-Frank Act, this vote is an advisory vote only and is not binding on the Company or its Board of Directors.

Although the vote is non-binding, the Compensation, Nominating and Corporate Governance Committee and the Board of Directors value your opinions and will consider the outcome of the vote in establishing compensation philosophy and making future compensation decisions.

The compensation of our named executive officers subject to the vote is disclosed in the Compensation Discussion and Analysis on pages 15 to 31 and in the Summary Compensation Table and subsequent tables on pages 22 to 29. As described more fully in those disclosures, our named executive officers, as identified on page 16, are compensated in a manner consistent with our business strategy, competitive practice, sound compensation governance principles and stockholder interests and concerns. Our compensation policies and decisions are focused on pay-for-performance principles and are strongly aligned with our stockholders' interests, consistent with current market practices.

The compensation of our named executive officers during our fiscal year ended December 31, 2012 is consistent with the Compensation, Nominating and Corporate Governance Committee's evaluation of our performance relative to the following 2012 corporate goals as described more fully in the Compensation Discussion and Analysis:

- continued commercialization of DIFICID, including specified levels of sales revenue;
- execution of our fidaxomicin market entry and launch strategy for key international markets;
- progression in meeting regulatory requirements and in supporting label expansion and life-cycle management of DIFICID; and
- advancement in our business development and financial management efforts.

We are requesting your non-binding vote on the following resolution:

"Resolved, that the compensation of the Company's named executive officers, as disclosed pursuant to Item 402 of Regulation S-K, including the Compensation Discussion and Analysis, compensation tables and narrative discussion, is hereby APPROVED."

Unless the Board of Directors decides to modify its policy regarding soliciting advisory votes on the compensation of the Company's named executives on an annual basis, the next scheduled say-on-pay vote will be at the 2014 Annual Meeting of Stockholders.

Advisory approval of this proposal requires the vote of the holders of a majority of the shares present in person or represented by proxy and entitled to vote at the Annual Meeting. Abstentions will be counted toward the tabulation of votes cast on this proposal and will have the same effect as negative votes. Broker non-votes are counted towards a quorum, but are not counted for any purpose in determining whether this matter has been approved.

THE BOARD OF DIRECTORS RECOMMENDS A VOTE IN FAVOR OF PROPOSAL 3.

# SECTION 16(A) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who own more than 10% percent of a registered class of our equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock and other equity securities. Officers, directors and greater than 10% stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file.

To our knowledge, based on a review of such reports filed with the SEC, all Section 16(a) forms required to be filed by our directors and executive officers and persons owning more than 10% of our common stock during 2012 were timely filed except that a grant of restricted stock units to Messrs. Auerbach and Altig, and Drs. Joseph Chang, Grebow, McKinnell and Zerbe was reported late for each individual because of an administrative error. In addition, one report relating to an open market purchase by Mr. Lichtinger and two reports related to transactions by Dr. Joseph Chang (one related to a gift and one related to an exercise of options and sale of common stock) were filed late.

# TRANSACTIONS WITH RELATED PERSONS

The following includes a description of transactions since January 1, 2012 to which we have been a party, in which the amount involved in the transaction exceeds \$120,000, and in which any of our directors, executive officers or holders of more than 5% of our capital stock, or any immediate family member of our directors, executive officers or holders of more than 5% of our capital stock, had or will have a direct or indirect material interest. We believe the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that would be paid or received, as applicable, in arm's-length transactions. We have adopted a written policy requiring that each director or executive officer report any such proposed transaction to the Board of Directors for prior approval. Absent approval by our Board of Directors, our Audit Committee generally reviews and approves in advance any proposed related party transactions. In determining whether to approve such a transaction, the following factors, among others, are considered:

- whether the transaction is fair and reasonable to us and on substantially the same terms as would apply to comparable third-parties;
- the business reasons for the transaction;
- whether the transaction would impair the independence of an independent director;
- whether the transaction presents a conflict of interest, taking into account the size of the transaction, the financial position of the director or executive officer, the nature of the director's or executive officer's interest in the transaction and the ongoing nature of the transaction;
- any disclosure or reputational issues; and
- whether the transaction is material, taking into account the significance of the transaction to our investors.

# Participation in OBI Direct Offerings

In February 2012, Mr. Lichtinger and funds in which Dr. Michael Chang has an ownership interest participated in a direct offering of stock by OBI. Mr. Lichtinger and funds in which Dr. Michael Chang has an ownership interest purchased 924,000 and 7,080,981, respectively, of the new shares at 15 New Taiwan Dollars per share, which is the same price paid by other participants of the offering.

In May 2012, we purchased the 924,000 shares of OBI from Mr. Lichtinger and canceled a restricted stock unit previously granted to Mr. Lichtinger covering an aggregate of 450,000 common shares of OBI, for an amount of cash equal to approximately \$0.5 million.

# Consulting Agreement with Michael Chang

In May 2010, we entered into a separation and consulting agreement with Dr. Michael Chang pursuant to which he provided general consulting services to us in exchange for compensation in the form of consulting fees of \$12,500 per month and stock options to purchase up to an aggregate of 400,000 shares of our common stock, which vested over time beginning on the dates certain regulatory filings were accepted and approved. Through March 31, 2012, 246,874 shares had vested. In April 2012, we terminated Dr. Michael Chang's consultancy arrangement with the Company and the unvested portion of his options was cancelled. However, due to Dr. Michael Chang's continuing role as a director, his other equity awards remain outstanding and continue to vest as per the vesting term of the awards.

# Separation Agreement with Tessie M. Che

In January 2012, we reached a mutual agreement with Tessie M. Che, Ph.D., our then-Chief Operating Officer and Senior Vice President and Dr. Michael Chang's wife, that she would cease employment with us effective immediately. We entered into a separation agreement with Dr. Che entitling her to receive severance benefits, which includes twenty-four months of salary continuation and reimbursement for medical benefits, an additional cash payment of \$130,900 related to a bonus for which she would have been eligible under our 2011 Incentive Compensation Plan, accelerated vesting and extended exercisability of outstanding equity awards and reimbursement for certain expenses.

# Transactions between Optimer Pharmaceuticals, Inc. and OBI

Dr. Michael Chang, who is one of our current directors and the former Chairman of our Board of Directors, is also an investor in, and the Chairman of the Board of Directors of, OBI. Below is a description of transactions between us and OBI:

In October 2009, we entered into an Intellectual Property Assignment and License Agreement with OBI pursuant to which we assigned to OBI certain patent rights, information and know-how related to OPT-88 and OPT-822/821. In anticipation of these transactions, we also assigned, and OBI assumed, our rights and obligations under related license agreements with Memorial Sloan-Kettering Cancer Center. Under the intellectual property assignment and license agreement, we are eligible to receive up to \$10 million in milestone payments related to the development of OPT-822-821 and are also eligible to receive royalties on net sales of any product which is commercialized under the programs. The term of the intellectual property assignment and license agreement continues until the last to expire of the patents assigned by us to OBI and the patents licensed to OBI.

In January 2012, we entered into a letter of agreement with OBI pursant to which OBI granted to us a right of first refusal if OBI or one of its affiliates receives any offer to obtain an exclusive, royalty-bearing license (including the right to sublicense) under the OPT-822/821 patents and the OBI OPT-822/821 technology to develop, make, have made, use, sell, offer for sale, have sold and import OPT-822/821 products in the United States, Europe or other specified territories. In the letter of agreement, as consideration for the grant of the right of first refusal, we waived certain of OBI's obligations under the intellectual property assignment and license agreement. The letter of agreement expires 10 years from the effective date of the agreement.

During a portion of 2012, we provided consulting, purchasing and other services to OBI and billed OBI in the amount of approximately \$89,000 for such services. As of December 31, 2012, the Company is no longer providing consulting, purchasing or other services to OBI.

In the fourth quarter of 2012, we sold our remaining ownership interest in OBI for \$60.0 million in gross proceeds, but retain our rights to receive milestone and royalty payments related to OPT-822/821 under the intellectual property assignment and license agreement. We also retain a right of first refusal to license commercial rights to OPT-822/821 in the United States, Europe or other specified territories.

# **Indemnification and Insurance**

We have entered into indemnification agreements with each of our executive officers and directors. These indemnification agreements require us to indemnify these individuals to the fullest extent permitted by Delaware law. In addition, we have purchased directors' and officers' liability insurance policies that insure our directors and officers against the cost of defense, settlement or payment of a judgment in some circumstances.

# HOUSEHOLDING OF PROXY MATERIALS

The SEC has adopted rules that permit companies and intermediaries (e.g., brokers) to satisfy the delivery requirements for proxy statements and annual reports with respect to two or more stockholders sharing the same address by delivering a single proxy statement addressed to those stockholders. This process, which is commonly referred to as "householding," potentially means extra convenience for stockholders and cost savings for companies.

This year, a number of brokers with account holders who are Optimer stockholders will be "householding" our proxy materials. A single proxy statement will be delivered to multiple stockholders sharing an address unless contrary instructions have been received from one or more of the affected stockholders. Once you have received notice from your broker that they will be "householding" communications to your address, "householding" will continue until you are notified otherwise or until you revoke your consent. If, at any time, you no longer wish to participate in "householding" and would prefer to receive a separate proxy statement and annual report, please notify your broker or Optimer and a separate copy will be sent to you promptly. Direct your written request to Optimer Pharmaceuticals, Inc., Attention: Corporate Secretary, 101 Hudson Street, Suite 3501, Jersey City, NJ 07302 or contact us at (201) 333-8819. Stockholders who currently receive multiple copies of the proxy statement at their addresses and would like to request "householding" of their communications should contact their brokers.

#### **OTHER MATTERS**

The Board of Directors knows of no other matters that will be presented for consideration at the Annual Meeting. If any other matters are properly brought before the Annual Meeting, it is the intention of the persons named in the accompanying proxy to vote on such matters in accordance with their best judgment.

By Order of the Board of Directors,

Henry A. McKinnell, Ph.D.

Chairman of the Board and Chief Executive Officer

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April 12, 2013

A copy of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2012 is available without charge upon written request to: Corporate Secretary, Optimer Pharmaceuticals, Inc., 101 Hudson Street, Suite 3501, Jersey City, NJ 07302.





Although the full impact of our efforts to improve patient access and address cost as a barrier will take time to realize, we believe we have positioned DIFICID for significant growth in 2013 and are excited about its potential as our strategy matures. In addition to improving patient access, other important elements of our continued growth include making DIFICID available on a global basis, advancing a robust life-cycle plan for fidaxomicin and clarifying our strategic focus.

Our efforts to commercialize fidaxomicin globally have been fruitful. We announced in July 2012 that our Canadian subsidiary, Optimer Canada, launched DIFICID in Canada in the third quarter. Outside of North America, we are partnered with Astellas Pharma Europe Limited (APEL) to commercialize fidaxomicin under the trade name DIFICLIR™ in Europe, the Commonwealth of Independent States, parts of Africa and the Middle East. As of year-end, APEL had launched DIFICLIR in 10 territories, including the U.K., Spain and France. We expect additional launches in 2013, including in Germany and Italy. In March 2012, we entered into a collaboration with Astellas Pharma Inc. for the commercialization of fidaxomicin in Japan. In June 2012, we entered into a distribution and license agreement with Specialised Therapeutics Australia to register and commercialize fidaxomicin in Australia and New Zealand. In the fourth quarter of 2012, we entered into an exclusive agreement with AstraZeneca to commercialize fidaxomicin in Latin America, including Brazil, Central America, Mexico and the Caribbean.

Critical to extending the DIFICID franchise is our life-cycle management program. In 2012, we initiated a Phase 3b clinical trial evaluating DIFICID for the prophylaxis, or prevention, of CDAD in patients undergoing hematopoietic stem cell transplant, often referred to as bone marrow transplantation. We believe that the use of DIFICID as a preventative treatment for CDAD has considerable clinical potential and that prophylaxis represents a potential opportunity for significant incremental market expansion.

Under our obligations and commitments to the FDA, we also are evaluating DIFICID in a Phase 2 pediatric pharmacokinetic trial and plan to initiate a study in patients suffering from multiple recurrences of CDAD later this year. We will continue to assess other areas for continued clinical evaluation of DIFICID, including studies to demonstrate superiority in clinical response for CDI in key patient sub-populations.

As we met the challenges of DIFICID commercialization with new initiatives, expansion of global fidaxomicin availability and initiation of our life-cycle management program, in 2012 we were also presented with some additional challenges. As has been previously disclosed, about a year ago, Optimer's Board became aware of an attempted grant of technical shares in Optimer Biotechnology, Inc. (OBI), our then majority-owned subsidiary in Taiwan, to our previous

Chairman. This prompted a review by the Board and resulted in the self-reporting of certain preliminary findings to the Securities and Exchange Commission and the Department of Justice. The ongoing review also led to additional remedial actions by the Board and resulted in management changes, including, most recently, my appointment as Chief Executive Officer.

Along with the rest of the Board, I continue to support Optimer's strategy for commercializing DIFICID. We have a great product, the right mix of programs to improve patient access and product adoption, and a talented and creative team that believes in DIFICID. With the appointment of new management, the Board determined that now is an appropriate time to explore a full range of strategic alternatives for maximizing the DIFICID opportunity. This review is not only timely in light of the changes at Optimer, but is in alignment with our overall commercialization process, which necessitates a periodic assessment of our efforts to make sure we are optimizing DIFICID's value for our stakeholders.

As we conduct our review, we intend to maintain our focus on DIFICID and the value we can deliver to our stockholders. We will further our leadership in creating and developing adaptive and innovative commercial programs that break down barriers to success, including challenges to patient access and product adoption. In addition, we will couple our ongoing focus on DIFICID with a continued dedication to strengthening our governance practices. In doing so, we believe Optimer can create a new benchmark for securing patient access to new and greatly needed antibiotics.

We appreciate the support from our stockholders and reinforce our commitment to stockholder value creation as we move forward.

Sincerely,

Hank McKinnell, Ph.D.

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Chairman of the Board and Chief Executive Officer

# **Executive Officers** Hank McKinnell, Ph.D. Chairman of the Board and

Chief Executive Officer

#### Stephen W. Webster

Chief Financial Officer and Senior Vice President, Finance

#### Sherwood L. Gorbach, M.D.

Chief Scientific Officer and Senior Vice President

# Meredith Schaum

General Counsel, Chief Compliance Officer

#### Linda E. Amper, Ph.D.

Senior Vice President, Human Resources

# Board of Directors Hank McKinnell, Ph.D.

Chairman of the Board and Chief Executive Officer

# Anthony E. Altig

Chief Financial Officer, Biotix Holdings, Inc.

#### Mark Auerbach

Director, Ventrus Biosciences, Inc.

#### Joseph Y. Chang, Ph.D.

Chief Scientific Officer and Executive Vice President of Product Development, Nu Skin Enterprises

# Michael N. Chang, Ph.D.

Co-Founder:

#### Peter E. Grebow, Ph.D.

P.E. Grebow Consulting, Inc.

#### Stephen Newman, M.D.

Member, Federal Reserve Bank of Atlanta's Labor Education and Healthcare Advisory Committee, and Director, Hansen Medical, Inc.

# Robert L. Zerbe, M.D.

President and Chief Executive Officer, QuatRx Pharmaceuticals Company

#### Headquarters

# Optimer Pharmaceuticals, Inc.

101 Hudson Street, Suite 3501 Jersey City, New Jersey 07302

#### 2013 Annual Meeting

The annual meeting of stockholders will be held at 8:00 a.m. Eastern Time on Wednesday, May 8, 2013 at the Grand Hyatt New York, 109 East 42nd Street at Grand Central Terminal, New York, New York, USA 10017

#### Stock Listing

# Exchange: Nasdaq Global Select Market

Symbol: OPTR

#### Transfer Agent

# American Stock Transfer & Trust Company

59 Maiden Lane New York, New York 10038 800-937-5449 www.amstock.com

#### Legal Counsel

#### Sullivan & Cromwell LLP

125 Broad Street New York, New York 10004-2498

#### Independent Auditor

### Ernest & Young, LLP

4370 La Jolla Village Drive Suite 500 San Diego, California 92122 This stockholder letter contains statements that discuss our future expectations and includes other forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Our actual results may differ significantly and materially from those expressed in these forward-looking statements as a result of risks and uncertainties, including those detailed in our Annual Report on Form 10-K. We disclaim any intent or obligation to update these forward-looking statements, and you should not unduly rely on them.