IDERA PHARMACEUTICALS, INC.
Form 10-K
March 14, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the Fiscal Year Ended December 31, 2011

OR

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the Transition Period from to

Commission File Number: 001-31918

IDERA PHARMACEUTICALS, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**04-3072298**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
167 Sidney Street **Cambridge, Massachusetts**	**02139** **(Zip Code)**
(Address of principal executive offices)	

(617) 679-5500

(Registrant s telephone number, including area code)

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

Title of Class:	Name of Each Exchange on Which Registered
Common Stock, $.001 par value	**NASDAQ Global Market**

(Including Associated Preferred Stock Purchase Rights)

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 þ

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

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 the filing requirements for the past 90 days. Yes þ No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes þ No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) 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. þ

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 þ	Non-accelerated filer ¨	Smaller reporting company ¨
		(Do not check if a 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 þ

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was $50,613,000 based on the last sale price of the registrant s common stock as reported on the NASDAQ Global Market on June 30, 2011. As of February 15, 2012, the registrant had 27,637,007 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant s Proxy Statement with respect to the Annual Meeting of Stockholders to be held on May 23, 2012 are incorporated by reference into Items 10, 11, 12, 13 and 14 of Part III of this Form 10-K.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains 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. All statements, other than statements of historical fact, included or incorporated in this report regarding our strategy, future operations, collaborations, intellectual property, financial position, future revenues, projected costs, prospects, plans, and objectives of management are forward-looking statements. The words believes, anticipates, estimates, plans, expects, intends, may, could, should, potential, likely, projects, continue, will, and would and similar expressions forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. There are a number of important factors that could cause our actual results to differ materially from those indicated or implied by forward-looking statements. These important factors include those set forth below under Part I, Item 1A Risk Factors. These factors and the other cautionary statements made in this Annual Report on Form 10-K should be read as being applicable to all related forward-looking statements whenever they appear in this Annual Report on Form 10-K. In addition, any forward-looking statements represent our estimates only as of the date that this Annual Report on Form 10-K is filed with the Securities and Exchange Commission and should not be relied upon as representing our estimates as of any subsequent date. We do not assume any obligation to update any forward-looking statements. We disclaim any intention or obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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PART I.

Item 1. ***Business***

Overview

We are a clinical stage biotechnology company engaged in the discovery and development of novel synthetic DNA- and RNA- based drug candidates. We are developing drug candidates that are designed to modulate immune responses mediated through Toll-like Receptors, or TLRs. We believe that the modulation of immune responses through TLRs provides a rationale for the development of drug candidates to treat a broad range of diseases. We are also evaluating gene silencing oligonucleotides, or GSOs, which inhibit the production of disease-associated proteins by targeting RNA. We believe that our GSO technology provides us with a platform from which drug candidates for diverse disease indications can be developed.

TLRs are specific receptors present in immune system cells. Using a chemistry-based approach, we have created synthetic DNA- and RNA-based compounds that are targeted to TLRs 3, 7, 8, and 9. A TLR agonist is a compound that stimulates an immune response through the targeted TLR. A TLR antagonist is a compound that blocks activation of an immune response through the targeted TLR. Drug candidates are compounds that we are developing and that have not been approved for any commercial use.

We are focusing our internal development efforts on TLR-targeted clinical candidates for autoimmune and inflammatory diseases and cancer, and on the advancement of our GSO technology platform. We are seeking to advance our TLR-targeted programs in infectious diseases, respiratory diseases, hematologic oncology, and the use of TLR3 agonists in vaccine adjuvant applications through collaborative alliances with pharmaceutical companies. We currently are collaborating with Merck Sharp & Dohme Corp. (formerly Merck & Co., Inc.), which is referred to herein as Merck, for the use of agonists of TLRs 7, 8, and 9 as vaccine adjuvants for cancer, infectious diseases, and Alzheimer s disease.

Autoimmune and Inflammatory Disease Program. We are developing IMO-3100, an antagonist of TLR7 and TLR9, for the treatment of psoriasis. We plan to conduct a Phase 2 clinical trial of IMO-3100 in adult patients with moderate to severe plaque psoriasis, randomized into three arms over a four-week treatment period, which we expect to initiate in the second quarter of 2012. In the trial, we plan to evaluate two dose levels of IMO-3100 and a concurrent placebo arm. In addition, we have selected IMO-8400, an antagonist of TLRs 7, 8, and 9, for development in the treatment of lupus. We are conducting nonclinical studies of IMO-8400 to support the submission of an Investigational New Drug Application, or IND, for IMO-8400. We expect to submit this IND to the United States Food and Drug Administration, or FDA, in the fourth quarter of 2012. We have evaluated IMO-3100 and IMO-8400 in preclinical models of several autoimmune diseases including psoriasis, lupus, rheumatoid arthritis, and multiple sclerosis. In these models, treatment with IMO-3100 or IMO-8400 was associated with improvement in a number of disease parameters.

Cancer Program. IMO-2055, an agonist of TLR9, is in clinical development for the treatment of cancer. In November 2011, we reacquired rights to IMO-2055 from Merck KGaA, Darmstadt, Germany, our former collaborator. We believe that IMO-2055 can be developed for use as an immune modifier in combination with targeted anticancer agents. Recently, we announced favorable data from a Phase 1b clinical trial of IMO-2055 in combination with erlotinib and bevacizumab in patients with advanced non-small cell lung cancer. We anticipate top-line data from a randomized Phase 2 clinical trial of IMO-2055 in combination with cetuximab in second-line patients with squamous cell carcinoma of the head and neck in the second quarter of 2012. We also expect to have top-line data from a Phase 1b clinical trial of IMO-2055 in combination with cetuximab and chemotherapy in patients with advanced colorectal cancer in the second quarter of 2012.

Gene Silencing Oligonucleotide Technology Platform. Our GSOs are single-stranded RNA or DNA constructs that are complementary to targeted mRNA sequences of therapeutic interest. In preclinical studies, our GSOs have inhibited in vivo gene expression without requiring a delivery enhancement technology.

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Additional Programs. In addition to our clinical programs in autoimmune and inflammatory diseases and in cancer, we have identified TLR drug candidates for applications in the treatment of infectious diseases, respiratory diseases and hematological malignancies, and TLR3 agonists for use as vaccine adjuvants. We are seeking to enter into collaborations with pharmaceutical companies to advance these applications.

Overview of the Human Immune System

The immune system protects the body by working through various mechanisms to recognize and eliminate bacteria, viruses and other infectious agents, referred to as pathogens, and abnormal cells such as cancer cells. These mechanisms initiate a series of signals resulting in stimulation of the immune system in response to the pathogens or abnormal cells. The activities of the immune system are undertaken by its two components: the innate immune system and the adaptive immune system.

The role of the innate immune system is to provide a rapid, non-specific response to a pathogen or to abnormal cells in the body and to activate the adaptive immune system. The innate immune system consists of specialized cells such as macrophages, dendritic cells and monocytes. When the body recognizes a pathogen, it activates cells of the innate immune system, resulting in a cascade of signaling events that cause the production of proteins such as cytokines to fight the infection caused by the pathogen. Unlike the antibodies and cellular responses produced by the adaptive immune system as described below, the proteins produced by the innate immune system are not pathogen-specific. Moreover, once the pathogen is eliminated and the infection is resolved, the innate immune system will not remember the pathogen.

In contrast to the innate immune system, the adaptive immune system provides a pathogen-specific response to an infection. The adaptive immune system does this through the recognition by certain immune cells of specific proteins, called antigens, which are part of the pathogen or abnormal cell. Signals produced by the innate immune system initiate this process. Upon recognition of an antigen, which could come from pathogens or from cancer cells, the adaptive immune system produces antibodies and antigen-specific immune cells that specifically detect and destroy cells that contain the antigen. This response is referred to as an antigen-specific immune response. An antigen-specific immune response normally takes several weeks to develop the first time. However, once developed, the adaptive immune system remembers the antigen. In this manner, if the pathogen again infects the body, the presence of the memory immunity will allow the adaptive immune system to respond again in a shorter period of time.

TLR-based Drug Discovery Technology

The human immune system is activated by recognizing pathogen-associated molecular patterns, or PAMPs. TLRs comprise a family of receptors that are known to recognize PAMPs. The different TLRs are expressed in various immune system cells and recognize different PAMPs. TLR9 is a receptor that specifically recognizes a PAMP that occurs in the DNA of bacteria and other pathogens, and compounds that mimic bacterial DNA. TLR3, TLR7, and TLR8 are receptors that recognize viral RNA and compounds that mimic viral RNA.

Based on our extensive experience in DNA and RNA chemistry, we are designing and creating novel synthetic DNA- and RNA-based compounds, which as a chemical class are called oligonucleotides. Some of our compounds are designed to be agonists of TLR3, 7, 8, or 9. Others of our compounds are designed to be antagonists to TLRs 7 and 8 or to TLRs 7, 8, and 9.

TLR7, TLR8, and TLR9 Antagonists

We have created novel classes of drug candidates that are designed to be antagonists of specific TLRs. Preclinical studies from independent researchers have suggested that TLR7 and TLR9 may play a role in some autoimmune and inflammatory diseases, and that TLR8 may contribute to regulation of TLR7. In cell-based experiments and animal models, our antagonist compounds have blocked immune stimulation mediated through

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TLR7 and TLR9, or through TLRs 7, 8, and 9. We have evaluated our antagonist drug candidates in preclinical mouse models of human autoimmune and inflammatory diseases including lupus, rheumatoid arthritis, multiple sclerosis, psoriasis, colitis, pulmonary inflammation, and hyperlipidemia. In these models, treatment with our antagonist drug candidates was associated with improvement in a number of disease parameters. IMO-3100, a dual antagonist of TLR7 and TLR9, is in clinical development for the treatment of psoriasis. IMO-8400, an antagonist of TLRs 7, 8, and 9, is our lead candidate for the treatment of lupus.

TLR9 Agonists

Drug candidates that are agonists of TLR9 and induce immune responses through TLR9 may be useful for the treatment or prevention of infectious diseases, cancer, and asthma and allergies, and may be used as vaccine adjuvants. We have created our TLR9 agonist candidates to activate specific cells of the immune system and produce cytokines and other proteins. These activated cells and the cytokines and other proteins they produce lead to stimulation of both the innate and the adaptive components of the immune system. Furthermore, in preclinical cell culture and animal model studies, we have shown that we can change the immunological activity of our TLR9 agonists by modifying the chemical structure of the molecule. We are using our ability to change immunological activity of our TLR9 agonists to create a growing portfolio of drug candidates that are potentially useful for treating or preventing different diseases. One of our TLR9 drug candidates is IMO-2055, which is in clinical development for the treatment of cancer.

TLR7 and TLR8 Agonists

We have created novel synthetic RNA-based compounds that are agonists of TLR7 or dual agonists of TLR7 and TLR8. These compounds are designed to mimic viral RNA. In preclinical studies in cell culture and animal models, these TLR7 and dual TLR7 and TLR8 agonists induced immune responses that we believe may be useful for to the treatment of cancer and infectious diseases and as vaccine adjuvants. We have studied a dual TLR7 and TLR8 agonist, which we refer to as IMO-4200, in preclinical models of hematological cancers. In preclinical models, we have observed antitumor activity of IMO-4200 as a monotherapy and in combination with selected targeted drugs currently approved for cancer treatment.

TLR3 Agonists

We have created a new class of double-stranded RNA-based compounds that act as agonists of TLR3, and are evaluating their potential use as vaccine adjuvants. Vaccines are composed of one or more antigens and one or more adjuvants in an appropriate formulation. The function of the adjuvants is to enhance immune recognition of the antigens and increase the ability of the immune system to make antigen-specific antibodies. In preclinical models, our TLR3 agonists elicited production of cytokines and other proteins. Additionally, our TLR3 agonists promoted increased production of antigen-specific antibodies and cytotoxic T cells compared to responses induced by the antigen alone in preclinical vaccination studies.

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Research and Development Programs

We are engaged in the evaluation of TLR-targeted drug candidates in multiple therapeutic areas. The following table summarizes the disease areas and the development status of our programs.

RESEARCH AND DEVELOPMENT PROGRAMS

Drug candidate(s)	Application	Development Status
Autoimmune and Inflammatory Diseases		
IMO-3100	Psoriasis	Phase 2 Clinical Trial Expected to be Initiated 2Q 2012
IMO-8400	Lupus	IND-enabling Development Ongoing
Cancer		
IMO-2055 plus cetuximab	Squamous Cell, Head and Neck	Phase 2 Clinical Trial
IMO-2055 plus erlotinib and bevacizumab	Non-small Cell Lung Cancer	Phase 1b Clinical Trial
IMO-2055 plus cetuximab and FOLFIRI	Colorectal Cancer	Phase 1b Clinical Trial
Vaccine Adjuvants		
TLR7, 8, and 9 agonists	Cancer, Infectious Diseases, Alzheimer s Disease	Research in Collaboration with Merck
TLR3 agonists	Infectious Diseases and Other Applications	Research
Gene Silencing Oligonucleotides	Inhibition of Gene Expression by Targeting RNA	Research

Cetuximab, erlotinib, and bevacizumab are marketed under the names Erbitux®, Tarceva®, and Avastin®, respectively.

Research and Development Programs

Autoimmune and Inflammatory Diseases

In autoimmune diseases such as lupus, psoriasis, and rheumatoid arthritis, the immune system forms autoantibodies to a molecule that is a normal part of the body. The autoantibodies may bind RNA, DNA, or complexes that contain RNA or DNA. Independent researchers have reported that TLR7 and TLR9 may recognize autoantibody complexes that contain RNA or DNA and induce further immune responses that include cytokine production, inflammation, and tissue damage. TLR8 may play a role in regulating the activity of TLR7. Independent researchers have also reported that patients with autoimmune diseases such as lupus, psoriasis, and rheumatoid arthritis have increased incidence of hyperlipidemia and other cardiovascular risk factors.

We have created DNA-based compounds that in preclinical studies act as antagonists of TLR7 and TLR9, such as IMO-3100, or as antagonists of TLRs 7, 8, and 9, such as IMO-8400. We believe that these antagonists may have application in the treatment of autoimmune diseases by inhibiting TLR7-, TLR8-, or TLR9-mediated responses to the autoantibody complexes that contain RNA or DNA and thereby interfering with the inflammatory disease progression caused by activation of the immune system.

We continue to evaluate our TLR antagonist drug candidates in various preclinical studies. We have shown that treatment with IMO-3100 was associated with improvement in a number of disease parameters in mouse models of psoriasis, lupus, arthritis, and other autoimmune and inflammatory diseases.

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In November 2009, we submitted to the FDA an IND for the clinical evaluation of IMO-3100 in autoimmune diseases. Since that time, we have conducted two Phase 1 clinical trials of IMO-3100. In a single-dose Phase 1 clinical trial in 36 healthy subjects, IMO-3100 was administered by subcutaneous injection at five dose levels. At each dose level, six subjects received IMO-3100. An additional six subjects received placebo treatment. In a four-week multiple dose trial in 24 healthy subjects, IMO-3100 was administered at either 0.64 mg/kg once per week or at 0.32 mg/kg twice per week, with eight subjects per regimen. Eight additional subjects received placebo injections. IMO-3100 was well tolerated at all dose levels in both trials. There were no treatment-related discontinuations or serious adverse events. Mild injection site reactions were the most frequent adverse event. In both trials, the intended target engagement of TLR7 and TLR9 was observed through inhibition of TLR7- and TLR9-mediated cytokine induction in peripheral blood mononuclear cells from study subjects following IMO-3100 treatment.

Following those Phase 1 clinical trials, we selected psoriasis as the initial autoimmune disease indication for further clinical evaluation of IMO-3100. In June 2011, we submitted a Phase 2 protocol to the FDA to conduct a 12-week clinical trial of IMO-3100 in patients with psoriasis. In July 2011, the FDA placed a clinical hold on the protocol that we had submitted. In October 2011, we submitted to FDA a new Phase 2 protocol to evaluate IMO-3100 in adult patients with moderate to severe plaque psoriasis, randomized into three arms, over a four-week treatment period. In December 2011, the FDA removed the clinical hold and we expect to initiate the four-week Phase 2 clinical trial in the second quarter of 2012. We plan to evaluate two dose levels of IMO-3100 and a concurrent placebo arm in the trial.

In addition to IMO-3100, we have selected IMO-8400, an antagonist of TLRs 7, 8, and 9, for development in the treatment of autoimmune diseases, with lupus as the initial disease indication. Currently we are conducting nonclinical studies to support submission of an IND for IMO-8400. We expect to submit the IND to the FDA in the fourth quarter of 2012. We have shown that treatment with IMO-8400 was associated with improvement in a number of disease parameters in mouse models of lupus, psoriasis, and arthritis. Specifically, in mouse models of lupus, IMO-8400 activity has been evidenced by increased survival, suppression of anti-DNA and anti-RNA antibodies and inflammatory cytokines, decreased tissue pathology, and improved renal function.

Cancer

The immune system is capable of recognizing cancer cells as abnormal cells, leading to an immune response. However, the body s immune response to cancer cells may be weak or absent. We believe that agonists of TLR7, TLR8, and TLR9 can enhance the body s immune response to cancer cells because TLRs are involved in stimulation of both innate and adaptive immunity.

IMO-2055, a TLR9 agonist, is our lead drug candidate for the treatment of cancer. In December 2007, we entered into an exclusive, worldwide license agreement with Merck KGaA to research, develop, and commercialize products containing our TLR9 agonists, including IMO-2055, for the treatment of cancer, excluding cancer vaccines. In July 2011, Merck KGaA informed us that, based on increased incidence of neutropenia and electrolyte imbalances reported in its Phase 1 trial of IMO-2055 in combination with cisplatin, 5-fluorouracil, and cetuximab in patients with first-line SCCHN, Merck KGaA had terminated the trial and re-evaluated its IMO-2055 clinical development program and, following such re-evaluation, had determined that it would not conduct further clinical development of IMO-2055. In November 2011, we regained global rights to IMO-2055 and our other TLR9 agonists, including preclinical lead drug candidates selected for further evaluation under the collaboration, for the treatment of cancer as part of an agreed-upon termination of our oncology collaboration with Merck KGaA.

During the collaboration period, Merck KGaA conducted clinical trials of IMO-2055 in combination with other anticancer agents in several cancer indications, including a Phase 1b trial of IMO-2055 in combination with erlotinib and bevacizumab in patients with advanced non-small cell lung cancer, or NSCLC, a Phase 1b clinical trial of IMO-2055 in combination with cetuximab and the chemotherapy regimen FOLFIRI in patients with advanced colorectal cancer, and an ongoing randomized Phase 2 trial of IMO-2055 in combination with cetuximab in patients with squamous cell carcinoma of the head and neck, or SCCHN. In January 2012, we

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announced favorable data from the Phase 1b clinical trial of IMO-2055 in combination with erlotinib and bevacizumab in patients with advanced NSCLC. In this trial, the combination of IMO-2055 with erlotinib and bevacizumab was well tolerated, and in the 33 patients who were evaluable for efficacy, the disease control rate was 79%. Median progression-free survival was 5.6 months and median overall survival was 16 months. These results compare favorably with recently published results of erlotinib plus bevacizumab in second-line treatment of patients with advanced NSCLC. We plan to present detailed results of the trial at an upcoming scientific meeting.

We anticipate top-line data from the ongoing Phase 2 clinical trial of IMO-2055 in combination with cetuximab in patients with SCCHN in the second quarter of 2012. In this study, 104 patients with SCCHN who had progressed on a cytotoxic therapy were randomized into two arms. In one arm, patients were treated with IMO-2055 at a dose of 0.32 mg/kg given once weekly subcutaneously in combination with weekly cetuximab. In the other arm of the study, patients were treated with cetuximab alone. The primary endpoint of the study is progression-free survival. Secondary outcome measures include overall response rate, disease control rate, overall survival, safety and tolerability in patients treated with IMO-2055 plus cetuximab compared to patients treated with cetuximab alone. In this study, crossover of the patients who progress on cetuximab alone is permitted to the combination arm of IMO-2055 plus cetuximab. The trial is being conducted at multiple centers in Europe and the United States.

We also expect to have in the second quarter of 2012 top-line data from the Phase 1b clinical trial of IMO-2055 in combination with cetuximab and the chemotherapy regimen FOLFIRI in patients with advanced colorectal cancer who have progressed following chemotherapy. The goal of this study was to establish a recommended Phase 2 dose of IMO-2055. Sixteen patients have been enrolled at three dose levels of IMO-2055 combined with cetuximab and FOLFIRI.

Clinical trials of IMO-2055 previously completed by us or by Merck KGaA include four Phase 1 clinical trials, of which two were in healthy subjects and two were in refractory cancer patients, and one Phase 2 clinical trial. The Phase 2 clinical trial was a monotherapy trial of IMO-2055 in patients with metastatic or recurrent clear cell renal cancer.

We plan to determine our next steps in the development of IMO-2055 after receiving the data from the Phase 2 clinical trial in SCCHN and from the Phase 1b clinical trial in colorectal cancer.

Vaccine Adjuvants TLR7, 8, and 9 Agonists

Vaccines are composed of one or more antigens and one or more adjuvants in an appropriate formulation. The function of the adjuvants is to enhance immune recognition of the antigens and increase the ability of the immune system to make antigen-specific antibodies.

In preclinical animal models, our TLR7, 8, and 9 agonists have shown adjuvant activity when combined with various types of antigens. Preclinical studies that we conducted with our TLR9 agonists and various antigens have shown improvements in several measures of antigen recognition, such as achievement of higher antibody levels, higher ratios of specific to nonspecific antibodies, and a reduction in the number of doses required to achieve effective antibody levels. We believe that agonists of TLRs 7, 8, and 9 have the potential to be used as adjuvants in vaccines.

In December 2006, we entered into a research collaboration with Merck Sharp & Dohme Corp., or Merck, and granted Merck an exclusive license to develop and commercialize our TLR7, 8, and 9 agonists by incorporating them in therapeutic and prophylactic vaccines being developed by Merck for cancer, infectious diseases, and Alzheimer s disease. The original term of the research collaboration was two years and Merck extended the research collaboration for two additional years to December 2010. During the four-year research collaboration period, multiple TLR agonists were created by us and evaluated by Merck against the criteria established in the license agreement. In January 2012, in accordance with the research collaboration, Merck selected multiple novel TLR7, 8, and 9 agonists for Merck s exclusive evaluation and use as vaccine adjuvants.

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Gene Silencing Oligonucleotides

Through our expertise in nucleic acid chemistry, we have designed and created a new class of molecules to inhibit gene expression. These gene silencing oligonucleotides, which we refer to as GSOs, are nucleic acid-based and represent a novel approach to selectively silence gene expression. We have studied our GSO compounds in multiple cell culture and animal models and observed potent gene silencing activity. We are actively engaged in preclinical research with our GSOs that is designed to explore their potential as research reagents and therapeutic agents.

In April 2011 we published a scientific paper in the Journal of Medicinal Chemistry describing the structure and gene silencing activity of our GSO compounds. In preclinical studies, we have demonstrated that our GSOs exert gene silencing activity in animals following systemic administration. Preclinical data also have shown that systemic delivery of GSOs targeted to the mRNA of apolipoprotein B and proprotein convertase subtilisin/kexin type 9, which are proteins associated with cardiovascular diseases, resulted in reduced serum total cholesterol and low-density-lipoprotein cholesterol in addition to reduced levels of the targeted mRNA and associated proteins. Additionally, in mouse models, systemic administration of GSOs showed significant specific gene-silencing activity with minimized induction of immune responses, as compared to other gene silencing approaches.

Additional Programs

In addition to our internal programs, we are seeking to advance our TLR-targeted programs in infectious diseases, hematologic oncology, respiratory diseases, and vaccine adjuvant applications only through partnerships with third parties.

Infectious Disease. Chronic HCV infection causes inflammation of the liver, which significantly increases the risk that a patient will develop liver failure or liver cancer. Recombinant interferon-alpha has been used as part of the standard of care treatment for chronic HCV infection. We and other independent researchers have shown in preclinical studies that TLR9 agonists induce many proteins, including natural interferon-alpha and other antiviral proteins.

IMO-2125, a synthetic DNA-based TLR9 agonist, was our lead candidate for the treatment of chronic hepatitis C virus, or HCV, infection. We conducted two Phase 1 clinical trials of IMO-2125 in patients with chronic HCV infection, one in patients with HCV who had not responded to prior treatment and one in combination with ribavirin, an antiviral medication approved for use in combination with interferon-alpha in the treatment of HCV infection, in treatment-naïve patients with genotype 1 chronic HCV infection. The primary objective of both trials was to assess the safety of IMO-2125. We also evaluated the effects of IMO-2125 on HCV RNA levels and on parameters of immune system activation. Data from both Phase 1 clinical trials have been presented in scientific meetings. During the third quarter of 2011, we re-assessed and prioritized our drug development programs and based on this prioritization, we discontinued further investment of internal resources on the development of IMO-2125 for the treatment of HCV.

Cancer. In addition to the use of TLR9 agonists in oncology applications, we selected IMO-4200 as a lead TLR7 and TLR8 agonist candidate for the treatment of hematological cancers. In preclinical models of lymphoma, IMO-4200 in combination with approved cancer treatments increased antitumor activity. We have conducted preclinical studies in mouse models combining IMO-4200 with ofatumumab, an anti-CD20 antibody, and, in separate experiments, with rituximab, an anti-CD20 antibody, plus a chemotherapy agent, fludarabine or bendamustine. In all of these combinations, IMO-4200 improved antitumor activity, increased survival, and enhanced the immunological mechanism of action of the antibody in preclinical models.

Respiratory Diseases. Asthma and allergy conditions are characterized by an imbalance of the immune system. Currently approved agents for the treatment of asthma and allergy conditions, including steroids and

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antibodies, are generally designed to suppress symptoms of asthmatic or allergic response. Our TLR9 agonists, by comparison, are designed to induce immune responses that could be useful in restoring immune system balance. In preclinical studies conducted by us and our collaborators, our TLR9 agonists caused improvements in multiple indices of allergic conditions. For example, in mouse models of allergy, our TLR9 agonists restored the balance of immunological activity, produced a higher ratio of specific versus non-specific antibodies, reduced the number of pulmonary immune cells that produce allergic inflammation, and improved lung function. IMO-2134 is our lead TLR9 agonist for asthma and allergies. The safety and pharmacodynamics of IMO-2134 have been evaluated in a Phase 1 clinical trial.

Vaccine Adjuvants. In addition to use of TLR7, 8, and 9 agonists as vaccine adjuvants, we also have created proprietary TLR3 agonists for potential use as vaccine adjuvants. In preclinical models, our TLR3 agonists stimulated immune responses, including promoting an increased production of antigen-specific antibodies and cytotoxic T cells as compared to responses induced by the antigen alone in preclinical vaccination studies.

Collaborative Alliances

An important part of our business strategy is to enter into research and development collaborations, licensing agreements, and other strategic alliances with biotechnology and pharmaceutical corporations that bring expertise and resources to the potential development and commercialization of drugs based on our technology. We were a party to a collaboration with Merck KGaA that was terminated in November 2011. We are currently party to a collaboration with Merck.

Merck KGaA

In December 2007, we entered into an exclusive, worldwide license agreement with Merck KGaA, Darmstadt, Germany, to research, develop and commercialize products containing our TLR9 agonists for the treatment of cancer, excluding cancer vaccines. Under the terms of the agreement, we granted Merck KGaA worldwide exclusive rights to our lead TLR9 agonists, IMO-2055 and IMO-2125, and to a specified number of novel follow-on TLR9 agonists to be identified by Merck KGaA and us under a research collaboration that ended in June 2010, for use in the treatment, cure and delay of the onset or progression of cancer in humans. Under the terms of the agreement:

- In February 2008, Merck KGaA paid us a $40.0 million upfront license fee in Euros of which we received $39.7 million due to foreign currency exchange rates;
- Merck KGaA agreed to reimburse future development costs for certain of our on-going IMO-2055 clinical trials, which we continued to conduct on behalf of Merck KGaA until September 2009;
- Merck KGaA agreed to pay us up to EUR 264 million in development, regulatory approval, and commercial success milestone payments if products containing our TLR9 agonist compounds are successfully developed and marketed for treatment, cure and/or delay of the onset or progression of cancer in humans; and
- Merck KGaA agreed to pay mid single-digit to low double-digit royalties on net sales of products containing our TLR9 agonists that are marketed.

In February 2009, we amended the license agreement with Merck KGaA so that we could initiate and conduct on behalf of Merck KGaA additional clinical trials of IMO-2055, until such time as Merck KGaA had filed an IND application with the FDA for IMO-2055 and assumed sponsorship of these trials. Under the amendment, Merck KGaA agreed to reimburse us for costs associated with any additional trials that we initiated and conducted. As of March 2010, Merck KGaA had assumed sponsorship of all clinical trials of IMO-2055 for the treatment of cancer and had taken responsibility for all further clinical development of IMO-2055 in the treatment of cancer, excluding vaccines.

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In November 2011, we and Merck KGaA entered into a termination agreement terminating the license agreement. Under the termination agreement,

- The license agreement was terminated and we regained all rights for developing TLR9 agonists for the treatment of cancer, including all rights to IMO-2055 and any follow-on TLR9 agonists;
- Merck KGaA agreed to continue to conduct the ongoing Phase 2 trial of IMO-2055 in combination with cetuximab and other specified related activities;
- We gained the rights to the data from the Phase 2 trial of IMO-2055 in combination with cetuximab, as well as to the data from the Phase 1 trials conducted in other cancer indications;
- We agreed to reimburse Merck KGaA a maximum of 1.8 million ($2.4 million at December 31, 2011) of Merck KGaA s costs for the third party contract research organization that is coordinating the ongoing Phase 2 trial of IMO-2055 in combination with cetuximab, payable in eleven installments comprised of ten monthly installments to be invoiced by Merck KGaA to us commencing on March 1, 2012 and a final payment payable by us to Merck KGaA upon Merck KGaA s completion of certain specified activities;
- We agreed to pay to Merck KGaA one-time 1.0 million ($1.3 million at December 31, 2011) milestone payments upon occurrence of each of the following milestones: (i) partnering of IMO-2055 between us and any third party, (ii) initiation of any Phase 2 or Phase 3 clinical trial for IMO-2055 and (iii) regulatory submission of IMO-2055 in any country; and
- Merck KGaA granted us an option to obtain a license to certain manufacturing and formulation know-how owned or developed by Merck KGaA under the License Agreement and to a Merck KGaA trademark. If we elect to exercise our option to either of these options, we will pay a low single digit royalty on net sales of IMO-2055, with respect to such licenses.

Merck Sharp & Dohme Corp. (Merck)

In December 2006, we entered into an exclusive license and research collaboration agreement with Merck to research, develop and commercialize vaccine products containing our TLR7, 8, and 9 agonists in the fields of cancer, infectious diseases and Alzheimer s disease. Under the terms of the agreement, we granted Merck worldwide exclusive rights to a number of our TLR7, 8, and 9 agonists for use in combination with Merck s therapeutic and prophylactic vaccines under development in the fields of cancer, infectious diseases, and Alzheimer s disease. There is no limit to the number of vaccines to which Merck can apply our agonists within these fields. We also agreed with Merck to engage in a two-year research collaboration to generate novel agonists targeting TLR7 and TLR8 and incorporating both Merck and the Company s chemistry for use in vaccines in the defined fields. Under the terms of the agreement, Merck extended the research collaboration for two additional years to December 2010. Under the terms of the agreement:

- Merck paid us a $20.0 million upfront license fee;
- Merck purchased $10.0 million of our common stock at $5.50 per share;
- Merck agreed to fund the research and development collaboration through its term;

Merck agreed to pay us milestone payments as follows:

up to $165.0 million if vaccines containing our TLR9 agonist compounds are successfully developed and marketed in each of the oncology, infectious disease and Alzheimer s disease fields;

up to $260.0 million if vaccines containing our TLR9 agonist compounds are successfully developed and marketed for follow-on indications in the oncology field and if vaccines containing our TLR7 or TLR8 agonists are successfully developed and marketed in each of the oncology, infectious disease, and Alzheimer s disease fields; and

if Merck develops and commercializes additional vaccines using our agonists, we would be entitled to receive additional milestone payments; and

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Merck agreed to pay us mid to upper single-digit royalties on net product sales of vaccines using our TLR agonist technology that are developed and marketed, with the royalty rates being dependent on disease indication and the TLR agonist employed.

Under the agreement, Merck is obligated to pay us royalties, on a product-by-product and country-by-country basis, until the later of the expiration of the patent rights licensed to Merck and the expiration of regulatory-based exclusivity for the vaccine product. If the patent rights and regulatory-based exclusivity expire in a particular country before the 10th anniversary of the product s first commercial sale in such country, Merck s obligation to pay us royalties will continue at a reduced royalty rate until such anniversary, except that Merck s royalty obligation will terminate upon the achievement of a specified market share in such country by a competing vaccine containing an agonist targeting the same toll-like receptor as that targeted by the agonist in the Merck vaccine. In addition, the applicable royalties may be reduced if Merck is required to pay royalties to third parties for licenses to intellectual property rights, which royalties exceed a specified threshold. Merck s royalty and milestone obligations may also be reduced if Merck terminates the agreement based on specified uncured material breaches by us.

Merck may terminate the collaborative alliance without cause upon 90 days written notice to us. Either party may terminate the collaborative alliance upon the other party s filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or for a material breach if such breach is not cured within 60 days after delivery of written notice.

In January 2012, in accordance with the agreement, Merck selected multiple novel TLR7, 8, and 9 agonists for Merck s exclusive evaluation and use as vaccine adjuvants.

Antisense Technology

We have been a pioneer in the development of antisense technology. We now are using our antisense expertise and technology to validate potential targets in the TLR signaling pathway. Antisense compounds may assist us in identifying drug candidates. We have identified antisense compounds targeted to human TLRs 2, 3, 4, 5, 7, 8, and 9 and to the TLR-associated signaling protein MyD88. We are studying these antisense compounds for potential applications in multiple disease indications.

We also believe that our antisense technology may be useful to pharmaceutical and biotechnology companies that are seeking to develop drug candidates that down-regulate gene targets discovered by, or proprietary to, such companies. Antisense drug candidates are designed to bind to RNA targets through hybridization, and decrease production of the specific protein encoded by the target RNA. We believe that drugs based on antisense technology may be more effective and cause fewer side effects than conventional drugs in applications with well-defined RNA targets because antisense drugs are designed to intervene in a highly specific fashion in the production of proteins, rather than after the proteins are made.

We have licensed specified rights related to antisense technology to certain parties. We also have in-licensed certain rights related to antisense technology.

Out-licenses. In 2001 we entered into an agreement with Isis Pharmaceuticals, Inc., under which we granted Isis a license, with the right to sublicense, to our antisense chemistry and delivery patents and patent applications; and we retained the right to use these patents and applications in our own drug discovery and development efforts and in collaborations with third parties. Isis paid us $15.0 million in cash and issued 857,143 shares of its common stock having an aggregate fair market value on the dates on which title to the shares was received of $17.3 million and is required to pay us a mid double-digit percentage of specified sublicense income it receives from some types of sublicenses of our patents and patent applications. To date, we have received $0.3 million in sublicense income from Isis. Also under the agreement, we licensed from Isis specified antisense patents and patent applications, principally Isis suite of RNase H patents and patent

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applications. We also paid to Isis $0.7 million and issued 1,005,499 shares of common stock having a fair market value of approximately $1.2 million on the date of issuance for this license and are obligated to pay Isis an annual maintenance fee and low single-digit royalties on net sales of antisense products sold that are covered by Isis s patent rights. We have the right to use these patents and patent applications in our drug discovery and development efforts and in some types of third-party collaborations. To date, we have only paid Isis annual maintenance fees and have not paid any royalties. The agreement may be terminated for an uncured material breach by either party. The licenses granted under the Isis agreement terminate upon the last to expire of the patents and patent applications licensed under the agreement. We may terminate at any time the sublicense by Isis to us of the patents and patent applications.

In addition, we are party to two other license agreements involving the license of our antisense patents and patent applications for antisense chemistry and delivery and for specific gene targets, under which we typically are entitled to receive license fees, sublicensing income, research payments, payments upon achievement of developmental milestones, and royalties on product sales.

In-licenses. Our principal in-license related to antisense technology is with University of Massachusetts Medical Center for antisense chemistry and for certain gene targets. Under the terms of our license agreement with University of Massachusetts Medical Center, we are the worldwide, exclusive licensee under a number of U.S. issued patents and various patent applications owned by University of Massachusetts Medical Center relating to the chemistry of antisense oligonucleotides and their use. This license expires upon the expiration of the last to expire of the patents covered by the license. Under the agreement, we have agreed to pay a low single-digit royalty on net product sales, a low double-digit percentage of any sublicense license income we receive, and a small annual license maintenance fee. Since 1999, we have paid approximately $1.7 million to University of Massachusetts Medical Center under this license agreement.

Additionally, we have entered into five other royalty-bearing license agreements under which we have acquired rights to antisense related patents, patent applications, and technology. Under all of these in-licenses, we are obligated to pay low to mid single-digit royalties on our net sales of products or processes covered by a valid claim of a licensed patent or patent application. Under some of these in-licenses, we are required to pay a low double-digit percentage of any sublicense income. All of our in-licenses impose various commercialization, sublicensing, insurance, and other obligations on us, and our failure to comply with these requirements could result in termination of the in-licenses.

Academic and Research Collaborations

We have entered into research collaborations with scientists at leading academic research institutions. These research collaborations allow us to augment our internal research capabilities and obtain access to specialized knowledge and expertise.

In general, our research collaborations may require us to supply compounds and pay various amounts to support the research. Under these research agreements, if a collaborator, solely or jointly with us, creates any invention, we may own exclusively such invention, have an automatic paid-up, royalty-free non-exclusive license or have an option to negotiate an exclusive, worldwide, royalty-bearing license to such invention. Inventions developed solely by our scientists in connection with research collaborations are owned exclusively by us. These collaborative agreements are non-exclusive and may be terminated with limited notice.

Research and Development Expenses

For the years ended December 31, 2011, 2010 and 2009, we spent approximately $18.0 million, $24.2 million, and $18.6 million on research and development activities. In 2009, Merck KGaA sponsored approximately $3.1 million of our research and development activities. In 2009, Merck sponsored approximately $0.8 million of our research and development activities. Sponsored research and development activities were minimal in 2011 and 2010.

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Patents, Proprietary Rights and Trade Secrets

Our success depends in part on our ability to obtain and maintain proprietary protection for our drug candidates, technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. We use a variety of methods to seek to protect our proprietary position, including filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. We also rely on trade secrets, know-how, continuing technological innovation, and in-licensing opportunities to develop and maintain our proprietary position.

We have devoted and continue to devote a substantial amount of our resources into establishing intellectual property protection for:

Novel chemical entities that function as agonists of TLR3, 7, 8 or 9;

Novel chemical entities that function as antagonists of TLR7, 8 or 9; and

Use of our novel chemical entities and chemical modifications to treat and prevent a variety of diseases.

As of March 1, 2012, we owned 78 U.S. patents and U.S. patent applications and 256 patents and patent applications throughout the rest of the world for our TLR-targeted immune modulation technologies. These patents and patent applications include novel chemical compositions of matter and methods of use for our immune modulatory compounds, including IMO-2055, IMO-2125, IMO-2134, IMO 3100, IMO-4200, and IMO-8400. To date, all of our intellectual property covering immune modulatory compositions and methods of their use is based on discoveries made solely by us. These patents expire at various dates ranging from 2017 to 2031. With respect to IMO-3100, we have patent applications that cover the chemical composition of matter of IMO-3100 and methods of its use that, if issued, would expire at the earliest in 2026. With respect to IMO-2055, we have issued patents that cover the chemical composition of matter of IMO-2055 and methods of its use, including in combination with marketed cancer products, with the earliest composition claims expiring in 2023. With respect to IMO-8400, we have patent applications that cover the chemical composition of matter of IMO-8400 and methods of its use that, if issued, would expire at the earliest in 2031.

As of March 1, 2012, we also own four U.S. patent applications and one corresponding worldwide patent application for our GSO compounds and methods of their use. Patents issuing from these applications, if any, would expire at their earliest in 2030.

In addition to our TLR-targeted patent portfolio, we are the owner or hold licenses of patents and patent applications related to antisense technology. As of March 1, 2012, our antisense patent portfolio included 100 U.S. patents and patent applications and 163 patents and patent applications throughout the rest of the world. These antisense patents and patent applications include novel compositions of matter, the use of these compositions for various genes, sequences and therapeutic targets, and oral and other routes of administration. Some of the patents and patent applications in our antisense portfolio were in-licensed. These in-licensed patents expire at various dates ranging from 2012 to 2022.

Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in each of our issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in these patent applications.

Litigation may be necessary to defend against or assert claims of infringement, to enforce patents issued to us, to protect trade secrets or know-how owned by us, or to determine the scope and validity of the proprietary rights of others or to determine the appropriate term for an issued patent. In addition, the U.S. Patent and Trademark Office, or USPTO, may declare interference proceedings to determine the priority of inventions with

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respect to our patent applications or reexamination or reissue proceedings to determine if the scope of a patent should be narrowed. Litigation or any of these other proceedings could result in substantial costs to and diversion of effort by us, and could have a material adverse effect on our business, financial condition and results of operations. These efforts by us may not be successful.

In January 2010, we filed a lawsuit against the USPTO in the United States District Court for the District of Columbia. In light of recent decisions in that court and the Court of Appeals for the Federal Circuit, we believe the USPTO assigned a shorter patent term to some of our U.S. patents than was allowed by law. We filed the lawsuit to obtain a determination of the appropriate patent term for these patents.

We may rely, in some circumstances, on trade secrets and confidentiality agreements to protect our technology. Although trade secrets are difficult to protect, wherever possible, we use confidential disclosure agreements to protect the proprietary nature of our technology. We regularly implement confidentiality agreements with our employees, consultants, scientific advisors, and other contractors and collaborators. However, there can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, or that our trade secrets and/or proprietary information will not otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may also arise as to the rights in related or resulting know-how and inventions.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, including any manufacturing changes, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, import and export of pharmaceutical products, such as those we are developing.

United States drug approval process

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, the Public Health Service Act and implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA s refusal to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement of profits or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests, animal studies and formulation studies in compliance with the FDA s good laboratory practice, or GLP, regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, for each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug for each indication;
- submission to the FDA of a new drug application, or NDA;

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satisfactory completion of an FDA advisory committee review, if applicable;

satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practices, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the drug s identity, strength, quality and purity; and

FDA review and approval of the NDA.

Nonclinical studies

Nonclinical studies include laboratory evaluation of product chemistry and formulation, as well as *in vitro* and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of nonclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. An IND sponsor must submit the results of the nonclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IND. Additional nonclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical trials

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB for each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health for public dissemination on their ClinicalTrials.gov website.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

Phase 1: The drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness.

Phase 2: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

Phase 3: The drug is administered to an expanded patient population in adequate and well-controlled clinical trials to generate sufficient data to statistically confirm the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 clinical trials may not be

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completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB s requirements or if the drug has been associated with unexpected serious harm to patients.

Marketing approval

Assuming successful completion of the required clinical testing, the results of the nonclinical and clinical studies, together with detailed information relating to the product s chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. Under federal law, the submission of most NDAs is additionally subject to a substantial application user fee, currently exceeding $1.8 million, and the sponsor of an approved NDA is also subject to annual product and establishment user fees, currently exceeding $98,000 per product and $520,000 per establishment. These fees are typically increased annually.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission before accepting them for filing to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to specified performance goals in the review of NDAs. Under these goals, the FDA has committed to review most such applications for non-priority products within 10 months, and most applications for priority review products, that is, drugs that the FDA determines represent a significant improvement over existing therapy, within six months. These performance goals likely will be extended by several months when the Prescription Drug User Fee Act is reauthorized in 2012. The review process may be extended by the FDA for three additional months to consider certain information or clarification regarding information already provided in the submission. The FDA may also refer applications for novel drugs or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. In addition, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP and integrity of the clinical data submitted.

The testing and approval process requires substantial time, effort and financial resources, and each may take many years to complete. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to develop our product candidates and secure necessary governmental approvals, which could delay or preclude us from marketing our products.

After the FDA s evaluation of the NDA and inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA s satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such

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resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval and refuse to approve the NDA.

Even if the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug s safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Fast track designation

The FDA is required to facilitate the development and expedite the review of drugs that are intended for the treatment of a serious or life-threatening condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the fast track program, the sponsor of a new drug candidate may request the FDA to designate the product for a specific indication as a fast track product concurrent with or after the filing of the IND for the product candidate. The FDA must determine if the product candidate qualifies for fast track designation within 60 days after receipt of the sponsor s request.

In addition to other benefits, such as the ability to use surrogate endpoints and have greater interactions with the FDA, the FDA may initiate review of sections of a fast track product s NDA before the application is complete. This rolling review is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA s time period goal for reviewing a fast track application does not begin until the last section of the NDA is submitted. In addition, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Priority review

Under FDA policies, a product candidate may be eligible for priority review, or review within a six-month time frame from the time a complete application is received. Products regulated by the FDA s Center for Drug Evaluation and Research, or CDER, are eligible for priority review if they provide a significant improvement compared to marketed products in the treatment, diagnosis or prevention of a disease. A fast track designated product candidate would ordinarily meet the FDA s criteria for priority review.

Accelerated approval

Under the FDA s accelerated approval regulations, the FDA may approve a drug for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit. In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

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Orphan drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally defined as a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the United States for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same orphan indication, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity in that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application user fee.

Pediatric information

Under the Pediatric Research Equity Act of 2003, as amended and reauthorized by the Food and Drug Administration Amendments Act of 2007, or the FDAAA, an NDA or supplement to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan drug designation.

The Hatch-Waxman Act

Abbreviated new drug applications

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant s product or a method of using the product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA. Generally, an ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths, dosage form and route of administration as the listed drug and has been shown to be bioequivalent through *in vitro* or *in vivo* testing or otherwise to the listed drug. ANDA applicants are not required to conduct or submit results of preclinical or clinical tests to prove the safety or effectiveness of their drug product, other than the requirement for bioequivalence testing. Drugs approved in this way are commonly referred to as generic equivalents to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA s Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable or will not be infringed by the new product.

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A certification that the new product will not infringe the already approved product s listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicate that it is not seeking approval of a patented method of use, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA also will not be approved until any applicable non-patent exclusivity period, such as exclusivity for obtaining approval of a new chemical entity, for the referenced product has expired. Federal law provides a period of five years following approval of a drug containing no previously approved active moiety during which ANDAs for generic versions of those drugs cannot be submitted unless the submission contains a Paragraph IV challenge to a listed patent, in which case the submission may be made four years following the original product approval. Federal law provides for a period of three years of exclusivity during which the FDA cannot grant effective approval of an ANDA if a listed drug contains a previously approved active moiety, but FDA requires as a condition of approval new clinical trials conducted by or for the sponsor. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication. Under the Best Pharmaceuticals for Children Act, federal law also provides that periods of patent and non-patent marketing exclusivity listed in the Orange Book for a drug may be extended by six months if the NDA sponsor conducts pediatric studies identified by the FDA in a written request. For written requests issued by the FDA after September 27, 2007, the date of enactment of the FDAAA, the FDA must grant pediatric exclusivity no later than nine months prior to the date of expiration of patent or non-patent exclusivity in order for the six-month pediatric extension to apply to that exclusivity period.

Section 505(b)(2) new drug applications

Most drug products obtain FDA marketing approval pursuant to an NDA or an ANDA. A third alternative is a special type of NDA, commonly referred to as a Section 505(b)(2) NDA, which enables the applicant to rely, in part, on the FDA s previous approval of a similar product, or published literature, in support of its application.

505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. If the 505(b)(2) applicant can establish that reliance on the FDA s previous approval is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. As a result, approval of a 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

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Combination products

The FDA regulates combinations of products that cross FDA centers, such as drug, biologic or medical device components that are physically, chemically or otherwise combined into a single entity, as a combination product. The FDA center with primary jurisdiction for the combination product will take the lead in the premarket review of the product, with the other center consulting or collaborating with the lead center.

The FDA s Office of Combination Products, or OCP, determines which center will have primary jurisdiction for the combination product based on the combination product s primary mode of action. A mode of action is the means by which a product achieves an intended therapeutic effect or action. The primary mode of action is the mode of action that provides the most important therapeutic action of the combination product, or the mode of action expected to make the greatest contribution to the overall intended therapeutic effects of the combination product.

Often it is difficult for the OCP to determine with reasonable certainty the most important therapeutic action of the combination product. In those difficult cases, the OCP will consider consistency with other combination products raising similar types of safety and effectiveness questions, or which center has the most expertise to evaluate the most significant safety and effectiveness questions raised by the combination product.

A sponsor may use a voluntary formal process, known as a Request for Designation, when the product classification is unclear or in dispute, to obtain a binding decision as to which center will regulate the combination product. If the sponsor objects to that decision, it may request that the agency reconsider that decision.

Other regulatory requirements

Any drug manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product s safety and effectiveness after commercialization. Regulatory approval of oncology products often requires that patients in clinical trials be followed for long periods to determine the overall survival benefit of the drug.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in

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revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical trials to assess new safety risks or imposition of distribution or other restrictions under a Risk Evaluation and Mitigation Strategy program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- consent decrees, injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses, and a company that is found to have improperly promoted off label uses may be subject to significant liability.

Additional provisions

Anti-kickback and false claims laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs. 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.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. 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 were 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, may also violate false claims laws. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Physician drug samples

As part of the sales and marketing process, pharmaceutical companies frequently provide samples of approved drugs to physicians. The Prescription Drug Marketing Act, or the PDMA, imposes requirements and

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limitations upon the provision of drug samples to physicians, as well as prohibits states from licensing distributors of prescription drugs unless the state licensing program meets certain federal guidelines that include minimum standards for storage, handling and record keeping. In addition, the PDMA sets forth civil and criminal penalties for violations.

Foreign regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

New legislation and regulations

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the testing, approval, manufacturing and marketing of products regulated by the FDA. For example, the FDAAA discussed above was enacted in 2007. In addition to new legislation, FDA regulations and policies are often revised or interpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether further legislative changes will be enacted or whether FDA regulations, guidance, policies or interpretations changed or what the effect of such changes, if any, may be.

Pharmaceutical coverage, pricing and reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we might obtain regulatory approval. Sales of any of our product candidates, if approved, will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government health programs such as Medicare and Medicaid, commercial health insurers and managed care organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product once coverage is approved. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the approved drugs for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor s decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Third-party reimbursement may not be sufficient to enable us to maintain price levels high enough to realize an appropriate return on our investment in product development.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. Third-party payors are increasingly challenging the prices

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charged for medical products and services and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. If these third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. Adoption of such controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals such as the drug candidates that we are developing and could adversely affect our net revenue and results.

Pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. There can be no assurance that any country that has price controls or reimbursement limitations for drug products will allow favorable reimbursement and pricing arrangements for any of our products.

The marketability of any products for which we might receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, an increasing emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on drug pricing. Coverage policies, third-party reimbursement rates and drug pricing regulation may change at any time. In particular, the Patient Protection and Affordable Care Act was enacted in the United States in March 2010 and contains provisions that may reduce the profitability of drug products, including, for example, increased rebates for drugs sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies share of sales to federal health care programs. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Manufacturing

We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of any of our drug candidates. We currently rely and expect to continue to rely on other companies for the manufacture of our drug candidates for preclinical and clinical development. We currently source our bulk drug manufacturing requirements from a limited number of contract manufacturers through the issuance of work orders on an as-needed basis. We depend and will continue to depend on our contract manufacturers to manufacture our drug candidates in accordance with cGMP regulations for use in clinical trials. We will ultimately depend on contract manufacturers for the manufacture of our products for commercial sale. Contract manufacturers are subject to extensive governmental regulation.

Under our collaborative agreement with Merck, Merck is responsible for manufacturing the drug candidates.

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Competition

We are developing our TLR-targeted drug candidates for use in the treatment of autoimmune and inflammatory diseases and cancer, and for use as vaccine adjuvants. For all of the disease areas in which we are developing potential therapies, there are many other companies, public and private, that are actively engaged in discovery, development, and commercializing products and technologies that may compete with our technologies and drug candidates and technology, including TLR targeted compounds as well as non-TLR targeted therapies.

Our principal competitors developing TLR-targeted compounds for autoimmune and inflammatory diseases include Dynavax Technologies Corporation, with its collaborator, GlaxoSmithKline plc., and for cancer treatment include Pfizer, Inc., and VentiRx Pharmaceuticals.

Merck s vaccines using our TLR7, 8 or 9 agonists as adjuvants may compete with vaccines using TLR agonists as adjuvants being developed or marketed by GlaxoSmithKline plc, Novartis, Dynavax Technologies Corporation, VaxInnate, Inc., Intercell AG, Cytos Biotechnology AG and Celldex Therapeutics, Inc.

Some of the potentially competitive products have been in development or commercialized for years, in some cases by large, well established pharmaceutical companies. Many of the marketed products have been accepted by the medical community, patients, and third-party payors. Our ability to compete may be affected by the previous adoption of such products by the medical community, patients, and third-party payors. Additionally, in some instances, insurers and other third-party payors seek to encourage the use of generic products, which makes branded products, such as our drug candidates, potentially less attractive, from a cost perspective, to buyers.

We recognize that other companies, including large pharmaceutical companies, may be developing or have plans to develop products and technologies that may compete with ours. Many of our competitors have substantially greater financial, technical, and human resources than we have. In addition, many of our competitors have significantly greater experience than we have in undertaking preclinical studies and human clinical trials of new pharmaceutical products, obtaining FDA and other regulatory approvals of products for use in health care and manufacturing, and marketing and selling approved products. Our competitors may discover, develop or commercialize products or other novel technologies that are more effective, safer or less costly than any that we are developing. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours.

We anticipate that the competition with our products and technologies will be based on a number of factors including product efficacy, safety, availability, and price. The timing of market introduction of our products and competitive products will also affect competition among products. We expect the relative speed with which we can develop products, complete the clinical trials, and approval processes and supply commercial quantities of the products to the market to be important competitive factors. Our competitive position will also depend upon our ability to attract and retain qualified personnel, to obtain patent protection or otherwise develop proprietary products or processes, and protect our intellectual property, and to secure sufficient capital resources for the period between technological conception and commercial sales.

Employees

As of March 1, 2012, we employed 26 individuals, 16 of whom are engaged in research and development and 16 of whom hold a Ph.D., M.D., or equivalent degree. None of our employees is covered by a collective bargaining agreement, and we consider relations with our employees to be good.

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Information Available on the Internet

Our internet address is www.iderapharma.com. The contents of our website are not part of this Annual Report on Form 10-K and our internet address is included in this document as an inactive textual reference. We make available free of charge through our web site our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to these reports filed or furnished pursuant to Section 12(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file or furnish such materials to the Securities and Exchange Commission.

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Item 1A. ***RISK FACTORS.***

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below in addition to the other information included or incorporated by reference in this Annual Report on Form 10-K before purchasing our common stock. If any of the following risks actually occurs, our business, financial condition or results of operations would likely suffer, possibly materially. In that case, the trading price of our common stock could fall, and you may lose all or part of the money you paid to buy our common stock.

Risks Relating to Our Financial Results and Need for Financing

We have incurred substantial losses and expect to continue to incur losses. We will not be successful unless we reverse this trend.

We have incurred losses in every year since our inception, except for 2002, 2008, and 2009 when our recognition of revenues under license and collaboration agreements resulted in our reporting net income for those years. As of December 31, 2011, we had an accumulated deficit of $375.4 million. Since January 1, 2001, we have primarily been involved in the development of our TLR pipeline. From January 1, 2001 through December 31, 2011, we incurred losses of $115.2 million. We incurred losses of $260.2 million prior to December 31, 2000 during which time we were primarily involved in the development of non-TLR targeted antisense technology. These losses, among other things, have had and will continue to have an adverse effect on our stockholders equity, total assets, and working capital.

We have never had any products of our own available for commercial sale and have received no revenues from the sale of drugs. To date, almost all of our revenues have been from collaborative and license agreements. We have devoted substantially all of our efforts to research and development, including clinical trials, and we have not completed development of any drug candidates. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses, whether or when any of our drug candidates will become commercially available, or when we will become profitable, if at all. We expect to incur substantial operating losses in future periods.

We will need additional financing, which may be difficult to obtain. Our failure to obtain necessary financing or doing so on unattractive terms could adversely affect our research and development programs and other operations.

We will require substantial funds to conduct research and development, including preclinical testing and clinical trials of our drug candidates. We will also require substantial funds to conduct regulatory activities and to establish commercial manufacturing, marketing, and sales capabilities. We had cash and cash equivalents of $24.6 million at December 31, 2011. We believe that our existing cash and cash equivalents will be sufficient to fund our operations at least into the first quarter of 2013 based on our current operating plan. We will need to raise additional funds in order to operate our business beyond such time. If we proceed with the clinical development of IMO-3100 beyond the planned Phase 2 trial, of IMO-2055 beyond the ongoing Phase 2 trial or of any of our other compounds, including IMO-8400, we expect that the period of time that our current resources would be able to fund our operations could be significantly reduced.

We expect to seek additional funding through collaborations, the sale or license of assets or financings of equity or debt securities. We believe that the key factors that will affect our ability to obtain additional funding are:

- the results of our clinical and preclinical development programs, including the results of the planned Phase 2 trial of IMO-3100 and the results of the ongoing Phase 2 trial of IMO-2055;

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developments related to our existing strategic collaboration with Merck;

the cost, timing, and outcome of regulatory reviews;

competitive and potentially competitive products and technologies and investors receptivity to our drug candidates and the technology underlying them in light of competitive products and technologies;

the receptivity of the capital markets to financings by biotechnology companies generally and companies with drug candidates and technologies such as ours specifically; and

our ability to enter into additional strategic collaborations with biotechnology and pharmaceutical companies and the success of such collaborations.

Additional financing may not be available to us when we need it or may not be available to us on favorable terms. We could be required to seek funds through collaborative alliances or through other means that may require us to relinquish rights to some of our technologies, drug candidates or drugs that we would otherwise pursue on our own. In addition, if we raise additional funds by issuing equity securities, our then existing stockholders will experience dilution. The terms of any financing may adversely affect the holdings or the rights of existing stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, and are likely to include rights that are senior to the holders of our common stock. Any additional debt financing or equity that we raise may contain terms, such as liquidation and other preferences, or liens or other restrictions on our assets, which are not favorable to us or our stockholders. If we are unable to obtain adequate funding on a timely basis or at all, we may be required to terminate, modify or delay preclinical or clinical trials of one or more of our drug candidates, fail to establish or delay the establishment of manufacturing, sale or marketing capabilities, curtail research and development programs for new drug candidates and/or possibly relinquish rights to portions of our technology, drug candidates and/or products. For example, we significantly curtailed expenditures on our research and development programs during 1999 and 2000 because we did not have sufficient funds available to advance these programs at planned levels.

Risks Relating to Our Business, Strategy and Industry

We are depending heavily on the development of IMO-3100 and IMO-2055 and on our collaborative alliance with Merck. If we or our collaborator decides to terminate the development of any of our drug candidates, are unable to successfully develop and commercialize our drug candidates, or experience significant delays in doing so, our business may be materially harmed.

We have invested a significant portion of our time and financial resources in the development of our clinical stage lead drug candidates, IMO-3100 and IMO-2055. We anticipate that our ability to generate product revenues will depend heavily on the successful development and commercialization of IMO-3100, IMO-2055 and the drug candidates being developed under our collaboration with Merck. Our efforts, and the efforts of Merck, to develop and commercialize these compounds are at an early stage and are subject to many challenges. In 2011, we experienced setbacks with respect to our programs for IMO-3100, IMO-2125 and IMO-2055, including:

During the fourth quarter of 2010, we commenced additional nonclinical studies of IMO-3100 in light of some reversible immune responses that were observed in the 13 week nonclinical toxicology studies and that were inconsistent with observations made in our other nonclinical studies of IMO-3100. In June 2011, we submitted a Phase 2 protocol to the FDA to conduct a 12-week clinical trial of IMO-3100 in patients with psoriasis. In July 2011, the FDA placed a clinical hold on the protocol that we had submitted.

In April 2011, we chose to delay initiation of our planned 12-week Phase 2 randomized clinical trial of IMO-2125 plus ribavirin in treatment-naïve, genotype 1 HCV patients based on preliminary observations in an ongoing 26-week chronic nonclinical toxicology study of IMO-2125 in rodents. We subsequently completed a 39-week chronic nonclinical toxicology study of IMO-2125 in non-human primates in which

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there were no similar observations. During the third quarter of 2011, we re-assessed and prioritized our drug development programs, and determined to discontinue further investment of internal resources on the development of IMO-2125 for the treatment of HCV.

In July 2011, Merck KGaA informed us that, based on increased incidence of neutropenia and electrolyte imbalances reported in its Phase 1 trial of IMO-2055 in combination with cisplatin/5-FU and cetuximab in patients with first-line SCCHN and subsequent re-evaluation of its clinical development program, Merck KGaA had determined that it would not conduct further clinical development of IMO-2055. In November 2011, we and Merck KGaA entered into a termination agreement terminating our collaboration.

In October 2011, we submitted to FDA a new Phase 2 protocol to evaluate IMO-3100 in adult patients with moderate to severe plaque psoriasis over a four-week treatment period. In December 2011, the FDA removed the clinical hold. We expect to initiate the four-week Phase 2 clinical trial in the second quarter of 2012. The outcome of this trial or the ongoing Phase 2 clinical trial of IMO-2055 being conducted by Merck KGaA could negatively impact our ability or willingness to proceed with the further development and commercialization of IMO-3100 or IMO-2055, as the case may be, or our ability to license such compounds to a third party. Moreover, with respect to IMO-3100, we cannot be certain that the FDA will allow us to conduct further clinical trials of IMO-3100 for treatment periods of more than four weeks or at all without additional clinical or preclinical data.

Our ability to successfully develop and commercialize these drug candidates, or other potential candidates, will depend on our ability to overcome these recent challenges and on several factors, including the following:

the drug candidates demonstrating an acceptable safety profile in nonclinical toxicology studies and during clinical trials;

timely enrollment in clinical trials of IMO-3100 and other drug candidates, which may be slower than anticipated, potentially resulting in significant delays;

satisfying conditions imposed on us and/or our collaborators by the FDA or equivalent foreign regulatory authorities regarding the scope or design of clinical trials;

the ability to demonstrate to the satisfaction of the FDA, or equivalent foreign regulatory authorities, the safety and efficacy of the drug candidates through current and future clinical trials;

timely receipt of necessary marketing approvals from the FDA and equivalent foreign regulatory authorities;

the ability to combine our drug candidates and the drug candidates being developed by Merck and any other collaborators safely and successfully with other therapeutic agents;

achieving and maintaining compliance with all regulatory requirements applicable to the products;

establishment of commercial manufacturing arrangements with third-party manufacturers;

the successful commercial launch of the drug candidates, assuming FDA approval is obtained, whether alone or in combination with other products;

acceptance of the products as safe and effective by patients, the medical community, and third-party payors;

competition from other companies and their therapies;

changes in treatment regimes;

successful protection of our intellectual property rights from competing products in the United States and abroad; and

a continued acceptable safety and efficacy profile of the drug candidates following marketing approval.

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If our clinical trials are unsuccessful, or if they are delayed or terminated, we may not be able to develop and commercialize our products.

In order to obtain regulatory approvals for the commercial sale of our products, we are required to complete extensive clinical trials in humans to demonstrate the safety and efficacy of our drug candidates. Clinical trials are lengthy, complex, and expensive processes with uncertain results. We may not be able to complete any clinical trial of a potential product within any specified time period. Moreover, clinical trials may not show our potential products to be both safe and efficacious. The FDA or other equivalent foreign regulatory agencies may not allow us to complete these trials or commence and complete any other clinical trials. For example, in July 2011, the FDA placed a clinical hold on a protocol we had submitted for a proposed Phase 2 clinical trial of IMO-3100 in patients with psoriasis.

The results from preclinical testing of a drug candidate that is under development may not be predictive of results that will be obtained in human clinical trials. In addition, the results of early human clinical trials may not be predictive of results that will be obtained in larger scale, advanced stage clinical trials. Furthermore, interim results of a clinical trial do not necessarily predict final results, and failure of any of our clinical trials can occur at any stage of testing. Companies in the biotechnology and pharmaceutical industries, including companies with greater experience in preclinical testing and clinical trials than we have, have suffered significant setbacks in clinical trials, even after demonstrating promising results in earlier trials. Moreover, effects seen in nonclinical studies, even if not observed in clinical trials, may result in limitations or restrictions on clinical trials. Numerous unforeseen events may occur during, or as a result of, preclinical testing, nonclinical testing or the clinical trial process that could delay or inhibit the ability to receive regulatory approval or to commercialize drug products.

In addition to the setbacks that we have experienced with respect to the clinical development of our TLR-targeted drug candidates, other companies developing drugs targeted to TLRs have experienced setbacks in clinical trials. For example in 2007, Coley Pharmaceutical Group, which since has been acquired by Pfizer, Inc., discontinued four clinical trials for PF-3512676, its investigational TLR9 agonist compound, in combination with cytotoxic chemotherapy in cancer, and suspended its development of a TLR9 agonist, Actilon®, for HCV infection. In July 2007, Anadys Pharmaceuticals, Inc. and its partner Novartis International Pharmaceutical, Ltd. (Novartis) announced that they had decided to discontinue the development of ANA975, the investigational TLR7 agonist compound for HCV infection. Dynavax Technologies Corporation announced in May 2008 discontinuation of the clinical development program for TOLAMBA®, which comprises a TLR9 agonist covalently attached to a ragweed antigen. These setbacks with respect to TLR-targeted drug candidates may result in enhanced scrutiny by regulators or IRBs of clinical trials of TLR-targeted drug candidates, including our TLR-targeted drug candidates, which could result in regulators or IRBs prohibiting the commencement of clinical trials, requiring additional nonclinical studies as a precondition to commencing clinical trials or imposing restrictions on the design or scope of clinical trials that could slow enrollment of trials, increase the costs of trials or limit the significance of the results of trials. Such setbacks could also adversely impact the desire of investigators to enroll patients in, and the desire of patients to enroll in, clinical trials of TLR-targeted drug candidates.

Other events that could delay or inhibit conduct of our clinical trials include:

- regulators or IRBs may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- nonclinical or clinical data may not be readily interpreted, which may lead to delays and/or misinterpretation;
- our nonclinical tests, including toxicology studies, or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional nonclinical testing or clinical trials or we may abandon projects that we expect may not be promising;
- the rate of enrollment or retention of patients in our clinical trials may be lower than we expect;

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we might have to suspend or terminate our clinical trials if the participating subjects experience serious adverse events or undesirable side effects or are exposed to unacceptable health risks;

regulators or IRBs may hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements, issues identified through inspections of manufacturing or clinical trial operations or clinical trial sites, or if, in their opinion, the participating subjects are being exposed to unacceptable health risks;

regulators may hold or suspend our clinical trials while collecting supplemental information on, or clarification of, our clinical trials or other clinical trials, including trials conducted in other countries or trials conducted by other companies;

we, along with our collaborators and subcontractors, may not employ, in any capacity, persons who have been debarred under the FDA s Application Integrity Policy, or similar policy under foreign regulatory authorities. Employment of such debarred persons, even if inadvertent, may result in delays in the FDA s or foreign equivalent s review or approval of our products, or the rejection of data developed with the involvement of such person(s);

the cost of our clinical trials may be greater than we currently anticipate; and

our products may not cause the desired effects or may cause undesirable side effects or our products may have other unexpected characteristics.

The rate of completion of clinical trials is dependent in part upon the rate of enrollment of patients. For example, in our Phase 1 clinical trial of IMO-2125 in patients with chronic HCV infection who had not responded to the current standard of care therapy, completion of each cohort took longer than anticipated due to enrollment procedures. Patient accrual is a function of many factors, including:

the size of the patient population;

the proximity of patients to clinical sites;

the eligibility criteria for the study;

the nature of the study, including the pattern of patient enrollment;

the existence of competitive clinical trials; and

the availability of alternative treatments.

We do not know whether clinical trials will begin as planned, will need to be restructured or will be completed on schedule, if at all. Significant clinical trial delays also could allow our competitors to bring products to market before we do and impair our ability to commercialize our products.

Delays in commencing clinical trials of potential products could increase our costs, delay any potential revenues, and reduce the probability that a potential product will receive regulatory approval.

Our drug candidates and our collaborators drug candidates will require preclinical and other nonclinical testing and extensive clinical trials prior to submission of any regulatory application for commercial sales. In conducting clinical trials, we cannot be certain that any planned clinical trial will begin on time, if at all. Delays in commencing clinical trials of potential products could increase our product development costs, delay any potential revenues, and reduce the probability that a potential product will receive regulatory approval.

Commencing clinical trials may be delayed for a number of reasons, including delays in:

manufacturing sufficient quantities of drug candidate that satisfy the required quality standards for use in clinical trials;

demonstrating sufficient safety to obtain regulatory approval for conducting a clinical trial;

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reaching an agreement with any collaborators on all aspects of the clinical trial;

reaching agreement with contract research organizations, if any, and clinical trial sites on all aspects of the clinical trial;

resolving any objections from the FDA or any regulatory authority on an IND application or proposed clinical trial design;

obtaining IRB approval for conducting a clinical trial at a prospective site; and

enrolling patients in order to commence the clinical trial.

The technologies on which we rely are unproven and may not result in any approved and marketable products.

Our technologies or therapeutic approaches are relatively new and unproven. We have focused our efforts on the research and development of RNA- and DNA-based compounds targeted to TLRs and on GSOs. Neither we nor any other company have obtained regulatory approval to market such compounds as therapeutic drugs, and no such products currently are being marketed. It is unknown whether the results of preclinical studies with TLR-targeted compounds will be indicative of results that may be obtained in clinical trials, and results we have obtained in the initial small-scale clinical trials we have conducted to date may not be predictive of results in subsequent large-scale clinical trials. Further, the chemical and pharmacological properties of RNA- and DNA-based compounds targeted to TLRs or of GSOs may not be fully recognized in preclinical studies and small-scale clinical trials, and such compounds may interact with human biological systems in unforeseen, ineffective or harmful ways that we have not yet identified.

As a result of these factors, we may never succeed in obtaining regulatory approval to market any product. Furthermore, the commercial success of any of our products for which we may obtain marketing approval from the FDA or other regulatory authorities will depend upon their acceptance by patients, the medical community, and third-party payors as clinically useful, safe, and cost-effective. In addition, if products being developed by our competitors have negative clinical trial results or otherwise are viewed negatively, the perception of our technologies and market acceptance of our products could be impacted negatively.

Our recent setbacks with respect to our TLR-targeted compounds, together with the setbacks experienced by other companies developing TLR-targeted compounds, may result in a negative perception of our technology and our TLR-targeted compounds, impact our ability to obtain marketing approval of these drug candidates and adversely affect acceptance of our technology and our TLR-targeted compounds by patients, the medical community and third-party payors.

Our efforts to educate the medical community on our potentially unique approaches may require greater resources than would be typically required for products based on conventional technologies or therapeutic approaches. The safety, efficacy, convenience, and cost-effectiveness of our products as compared to competitive products will also affect market acceptance.

We face substantial competition, which may result in others discovering, developing or commercializing drugs before or more successfully than us.

We are developing our TLR-targeted drug candidates for use in the treatment of autoimmune and inflammatory diseases and cancer, and as vaccine adjuvants. We are also advancing our gene silencing oligonucleotide, or GSO, technology for potential application as research reagents and as therapeutic agents. For all of the disease areas in which we are developing potential therapies, there are many other companies, public and private, that are actively engaged in discovering, developing, and commercializing products and technologies that may compete with our technologies and drug candidates and technology, including TLR targeted compounds as well as non-TLR targeted therapies.

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Our principal competitors developing TLR-targeted compounds for autoimmune and inflammatory diseases include Dynavax Technologies Corporation, with its collaborator, GlaxoSmithKline plc., and for cancer treatment include Pfizer, Inc., and VentiRx Pharmaceuticals. Merck s vaccines using our TLR7, 8 or 9 agonists as adjuvants may compete with vaccines using TLR agonists as adjuvants being developed or marketed by GlaxoSmithKline plc, Novartis, Dynavax Technologies Corporation, VaxInnate, Inc., Intercell AG, Cytos Biotechnology AG, and Celldex Therapeutics, Inc.

Some of these potentially competitive products have been in development or commercialized for years, in some cases by large, well established pharmaceutical companies. Many of the marketed products have been accepted by the medical community, patients, and third-party payors. Our ability to compete may be affected by the previous adoption of such products by the medical community, patients, and third-party payors. Additionally, in some instances, insurers and other third-party payors seek to encourage the use of generic products, which makes branded products, such as our drug candidates, potentially less attractive, from a cost perspective, to buyers.

We recognize that other companies, including large pharmaceutical companies, may be developing or have plans to develop products and technologies that may compete with ours. Many of our competitors have substantially greater financial, technical, and human resources than we have. In addition, many of our competitors have significantly greater experience than we have in undertaking preclinical studies and human clinical trials of new pharmaceutical products, obtaining FDA and other regulatory approvals of products for use in health care and manufacturing, and marketing and selling approved products. Our competitors may discover, develop or commercialize products or other novel technologies that are more effective, safer or less costly than any that we are developing. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours.

We anticipate that the competition with our products and technologies will be based on a number of factors including product efficacy, safety, availability, and price. The timing of market introduction of our products and competitive products will also affect competition among products. We expect the relative speed with which we can develop products, complete the clinical trials, and approval processes and supply commercial quantities of the products to the market to be important competitive factors. Our competitive position will also depend upon our ability to attract and retain qualified personnel, to obtain patent protection or otherwise develop proprietary products or processes, and protect our intellectual property, and to secure sufficient capital resources for the period between technological conception and commercial sales.

Competition for technical and management personnel is intense in our industry, and we may not be able to sustain our operations or grow if we are unable to attract and retain key personnel.

Our success is highly dependent on the retention of principal members of our technical and management staff, including Dr. Sudhir Agrawal. Dr. Agrawal serves as our Chairman of the Board of Directors, President and Chief Executive Officer. Dr. Agrawal has made significant contributions to the field of oligonucleotide-based drug candidates, and has led the discovery and development of our compounds targeted to TLRs. He is named as an inventor on over 400 patents and patent applications in countries around the world. Dr. Agrawal provides us with leadership for our management team and research and development activities. The loss of Dr. Agrawal s services would be detrimental to our ongoing scientific progress and the execution of our business plan.

We are a party to an employment agreement with Dr. Agrawal that expires on October 19, 2014, but automatically extends annually for an additional year. This agreement may be terminated by us or Dr. Agrawal for any reason or no reason at any time upon notice to the other party. We do not carry key man life insurance for Dr. Agrawal.

Furthermore, our future growth will require hiring a number of qualified technical and management personnel. Accordingly, recruiting and retaining such personnel in the future will be critical to our success. There

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is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. If we are not able to continue to attract and retain, on acceptable terms, the qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or growth.

Regulatory Risks

We may not be able to obtain marketing approval for products resulting from our development efforts.

All of the drug candidates that we are developing, or may develop in the future, will require additional research and development, extensive preclinical studies, nonclinical testing, clinical trials, and regulatory approval prior to any commercial sales. This process is lengthy, often taking a number of years, is uncertain, and is expensive. Since our inception, we have conducted clinical trials of a number of compounds. Currently two of our compounds, IMO-3100 and IMO-2055, are in clinical development. The FDA and other regulatory authorities may not approve any of our potential products for any indication.

We may need to address a number of technological challenges in order to complete development of our products. Moreover, these products may not be effective in treating any disease or may prove to have undesirable or unintended side effects, unintended alteration of the immune system over time, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use. If we do not obtain necessary regulatory approvals, our business will be adversely affected.

We are subject to comprehensive regulatory requirements, which are costly and time consuming to comply with; if we fail to comply with these requirements, we could be subject to adverse consequences and penalties.

The testing, manufacturing, labeling, advertising, promotion, export, and marketing of our products are subject to extensive regulation by governmental authorities in Europe, the United States, and elsewhere throughout the world.

In general, submission of materials requesting permission to conduct clinical trials may not result in authorization by the FDA or any equivalent foreign regulatory agency to commence clinical trials. Further, permission to continue ongoing trials may be withdrawn by the FDA or other regulatory agencies at any time after initiation, based on new information available after the initial authorization to commence clinical trials or for other reasons. In addition, submission of an application for marketing approval to the relevant regulatory agency following completion of clinical trials may not result in the regulatory agency approving the application if applicable regulatory criteria are not satisfied, and may result in the regulatory agency requiring additional testing or information.

Even if we obtain regulatory approval for any of our product candidates, we will be subject to ongoing FDA obligations and regulatory oversight. Any regulatory approval of a product may contain limitations on the approved indicated uses for which the product may be marketed or requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Any product for which we obtain marketing approval, along with the facilities at which the product is manufactured, any post-approval clinical data, and any advertising and promotional activities for the product will be subject to continual review and periodic inspections by the FDA and other regulatory agencies.

Both before and after approval is obtained, failure to comply with regulatory requirements, or discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, may result in:

- the regulatory agency s delay in approving, or refusal to approve, an application for marketing of a product or a supplement to an approved application;

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restrictions on our products or the marketing or manufacturing of our products;

withdrawal of our products from the market;

warning letters;

voluntary or mandatory product recalls;

fines;

suspension or withdrawal of regulatory approvals;

product seizure or detention;

refusal to permit the import or export of our products;

injunctions or the imposition of civil penalties; and

criminal penalties.

We have only limited experience in regulatory affairs and our products are based on new technologies; these factors may affect our ability or the time we require to obtain necessary regulatory approvals.

We have only limited experience in filing the applications necessary to obtain regulatory approvals. Moreover, the products that result from our research and development programs will likely be based on new technologies and new therapeutic approaches that have not been extensively tested in humans. The regulatory requirements governing these types of products may be more rigorous than for conventional drugs. As a result, we may experience a longer regulatory process in connection with obtaining regulatory approvals of any product that we develop.

Failure to obtain regulatory approval in jurisdictions outside the United States will prevent us from marketing our products abroad.

We intend to market our products, if approved, in markets outside the United States, which will require separate regulatory approvals and compliance with numerous and varying regulatory requirements. The approval procedures vary among such markets and may involve requirements for additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all.

Risks Relating to Collaborators

If we are unable to establish additional collaborative alliances, our business may be materially harmed.

We seek to advance some of our products through collaborative alliances with pharmaceutical companies. Collaborators provide the necessary resources and drug development experience to advance our compounds in their programs. During the third quarter of 2011, we decided to advance our TLR-targeted programs in infectious diseases, respiratory diseases, hematologic oncology, and additional vaccine adjuvant applications only through partnerships with third parties.

Upfront payments and milestone payments received from collaborations help to provide us with the financial resources for our internal research and development programs. Our internal programs are focused on developing TLR-targeted drug candidates for the potential treatment of autoimmune and inflammatory diseases and cancer. We are also advancing our GSO technology for potential application as research reagents and as

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therapeutic agents. We believe that additional resources will be required to advance compounds in all of these areas. If we do not reach agreements with additional collaborators in the future, we may not be able to obtain the expertise and resources necessary to achieve our business objectives, our ability to advance our compounds will be jeopardized and we may fail to meet our business objectives.

We may have difficulty establishing additional collaboration alliances, particularly with respect to our TLR-targeted drug candidates and technology. Potential partners may note that our TLR collaborations with Novartis and with Merck KGaA have been terminated. Potential partners may also be reluctant to establish collaborations with respect to IMO-2125, IMO-3100, and our other TLR-targeted drug candidates, given our recent setbacks with respect to IMO-3100, IMO-2055 and IMO-2125. We also face, and expect to continue to face, significant competition in seeking appropriate collaborators.

Even if a potential partner were willing to enter into a collaborative alliance with respect to our TLR-targeted compounds or technology, the terms of such a collaborative alliance may not be on terms that are favorable to us. Moreover, collaborations are complex and time consuming to negotiate, document, and implement. We may not be successful in our efforts to establish and implement collaborations on a timely basis.

Our existing collaboration and any collaborations we enter into in the future may not be successful.

An important element of our business strategy includes entering into collaborative alliances with corporate collaborators, primarily large pharmaceutical companies, for the development, commercialization, marketing, and distribution of some of our drug candidates. In December 2007, we entered into an exclusive, worldwide license agreement with Merck KGaA to research, develop, and commercialize products containing our TLR9 agonists for treatment of cancer, excluding cancer vaccines. In December 2006, we entered into an exclusive license and research collaboration with Merck to research, develop, and commercialize vaccine products containing our TLR7, 8, and 9 agonists in the fields of cancer, infectious diseases, and Alzheimer s disease.

Any collaboration that we enter into may not be successful. For instance, in July 2011, Merck KGaA informed us that it had determined not to conduct further clinical development of IMO-2055, and in November 2011, we entered into an agreement with Merck KGaA terminating our collaboration with them. The success of our collaborative alliances, if any, will depend heavily on the efforts and activities of our collaborators. Our existing collaboration and any potential future collaborations have risks, including the following:

- our collaborators may control the development of the drug candidates being developed with our technologies and compounds including the timing of development;
- our collaborators may control the public release of information regarding the developments, and we may not be able to make announcements or data presentations on a schedule favorable to us;
- disputes may arise in the future with respect to the ownership of rights to technology developed with our collaborators;
- disagreements with our collaborators could delay or terminate the research, development or commercialization of products, or result in litigation or arbitration;
- we may have difficulty enforcing the contracts if any of our collaborators fail to perform;
- our collaborators may terminate their collaborations with us, which could make it difficult for us to attract new collaborators or adversely affect the perception of us in the business or financial communities;
- our collaboration agreements are likely to be for fixed terms and subject to termination by our collaborators in the event of a material breach or lack of scientific progress by us;

our collaborators may have the first right to maintain or defend our intellectual property rights and, although we would likely have the right to assume the maintenance and defense of our intellectual property rights if our collaborators do not, our ability to do so may be compromised by our collaborators acts or omissions;

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our collaborators may challenge our intellectual property rights or utilize our intellectual property rights in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential liability;

our collaborators may not comply with all applicable regulatory requirements, or may fail to report safety data in accordance with all applicable regulatory requirements;

our collaborators may change the focus of their development and commercialization efforts. Pharmaceutical and biotechnology companies historically have re-evaluated their priorities following mergers and consolidations, which have been common in recent years in these industries. For example, we have a strategic partnership with Merck, which merged with Schering-Plough, which has been involved with certain TLR-targeted research and development programs. Although the merger has not affected our partnership with Merck to date, management of the combined company could determine to reduce the efforts and resources that the combined company will apply to its strategic partnership with us or terminate the strategic partnership. The ability of our products to reach their potential could be limited if our collaborators decrease or fail to increase spending relating to such products;

our collaborators may under fund or not commit sufficient resources to the testing, marketing, distribution or development of our products; and

our collaborators may develop alternative products either on their own or in collaboration with others, or encounter conflicts of interest or changes in business strategy or other business issues, which could adversely affect their willingness or ability to fulfill their obligations to us.

Given these risks, it is possible that any collaborative alliance into which we enter may not be successful. Collaborations with pharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. For example, effective as of February 2010, Novartis terminated the research collaboration and option agreement that we entered into with it in May 2005, and in November 2011, we entered into an agreement with Merck KGaA terminating our collaboration with them. In addition, Merck may terminate its license and research collaboration agreement by giving us 90 days advance notice. The termination or expiration of our agreement with Merck or any other collaboration agreement that we enter into in the future may adversely affect us financially and could harm our business reputation.

Risks Relating to Intellectual Property

If we are unable to obtain patent protection for our discoveries, the value of our technology and products will be adversely affected.

Our patent positions, and those of other drug discovery companies, are generally uncertain and involve complex legal, scientific, and factual questions. Our ability to develop and commercialize drugs depends in significant part on our ability to:

obtain patents;

obtain licenses to the proprietary rights of others on commercially reasonable terms;

operate without infringing upon the proprietary rights of others;

prevent others from infringing on our proprietary rights; and

protect our trade secrets.

We do not know whether any of our patent applications or those patent applications that we license will result in the issuance of any patents. Our issued patents and those that may be issued in the future, or those licensed to us, may be challenged, invalidated or circumvented, and the rights granted thereunder may not

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provide us proprietary protection or competitive advantages against competitors with similar technology. Moreover, intellectual property laws may change and negatively impact our ability to obtain issued patents covering our technologies or to enforce any patents that issue. Because of the extensive time required for development, testing, and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thus reducing any advantage provided by the patent.

Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that we or they were the first to make the inventions claimed in issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in these patent applications.

As of March 1, 2012, we owned 78 U.S. patents and U.S. patent applications and 256 corresponding patents and patent applications throughout the rest of the world for our TLR-targeted immune modulation technologies. These patents and patent applications include novel chemical compositions of matter and methods of use of our IMO compounds, including IMO-3100, IMO-2055, and IMO-8400. With respect to IMO-3100, we have patent applications that cover the chemical composition of matter of IMO-3100 and methods of its use that, if issued, would expire at the earliest in 2026. With respect to IMO-2055, we have issued patents that cover the chemical composition of matter of IMO-2055 and methods of its use, including in combination with marketed cancer products, with the earliest composition claims expiring in 2023. With respect to IMO-8400, we have patent applications that cover the chemical composition of matter of IMO-8400 and methods of its use that, if issued, would expire at the earliest in 2031.

As of March 1, 2012, we owned four U.S. patent applications and one worldwide patent application for our GSO compounds and methods of their use. Patents issuing from these patent applications, if any, would expire at the earliest in 2030.

In addition to our TLR-targeted and GSO patent portfolios, we are the owner or hold licenses of patents and patent applications related to antisense technology. As of March 1, 2012, our antisense patent portfolio included 100 U.S. patents and patent applications and 163 patents and patent applications throughout the rest of the world. These antisense patents and patent applications include novel compositions of matter, the use of these compositions for various genes, sequences and therapeutic targets, and oral and other routes of administration. Some of the patents and patent applications in our antisense portfolio were in-licensed. These in-licensed patents expire at various dates ranging from 2012 to 2022.

Third parties may own or control patents or patent applications and require us to seek licenses, which could increase our development and commercialization costs, or prevent us from developing or marketing products.

Although we have many issued patents and pending patent applications in the United States and other countries, we may not have rights under certain third party patents or patent applications related to our products. Third parties may own or control these patents and patent applications in the United States and abroad. In particular, we are aware of third party United States patents that contain broad claims related to the use of certain oligonucleotides for stimulating an immune response, although we do not believe that these claims are valid. In addition, there may be other patents and patent applications related to our products of which we are not aware. Therefore, in some cases, in order to develop, manufacture, sell or import some of our products, we or our collaborators may choose to seek, or be required to seek, licenses under third-party patents issued in the United States and abroad or under third party patents that might issue from United States and foreign patent applications. In such an event, we would be required to pay license fees or royalties or both to the licensor. If licenses are not available to us on acceptable terms, we or our collaborators may not be able to develop, manufacture, sell or import these products.

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We may lose our rights to patents, patent applications or technologies of third parties if our licenses from these third parties are terminated. In such an event, we might not be able to develop or commercialize products covered by the licenses.

Currently, we have not in-licensed any patents or patent applications related to our TLR-targeted drug candidate programs or our GSO compounds and methods of their use. However, we are party to six royalty-bearing license agreements under which we have acquired rights to patents, patent applications, and technology of third parties in the field of antisense technology, which may be applicable to our TLR antisense. Under these licenses we are obligated to pay royalties on net sales by us of products or processes covered by a valid claim of a patent or patent application licensed to us. We also are required in some cases to pay a specified percentage of any sublicense income that we may receive. These licenses impose various commercialization, sublicensing, insurance, and other obligations on us.

Our failure to comply with these requirements could result in termination of the licenses. These licenses generally will otherwise remain in effect until the expiration of all valid claims of the patents covered by such licenses or upon earlier termination by the parties. The issued patents covered by these licenses expire at various dates ranging from 2012 to 2022. If one or more of these licenses is terminated, we may be delayed in our efforts, or be unable, to develop and market the products that are covered by the applicable license or licenses.

We may become involved in expensive patent litigation or other proceedings, which could result in our incurring substantial costs and expenses or substantial liability for damages or require us to stop our development and commercialization efforts.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the biotechnology industry. We may become a party to various types of patent litigation or other proceedings regarding intellectual property rights from time to time even under circumstances where we are not practicing and do not intend to practice any of the intellectual property involved in the proceedings. For instance, in 2002, 2003, and 2005, we became involved in interference proceedings declared by the United States Patent and Trademark Office for some of our antisense and ribozyme patents. All of these interferences have since been resolved. We are neither practicing nor intending to practice the intellectual property that is associated with any of these interference proceedings.

The cost to us of any patent litigation or other proceeding even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the cost of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. If any patent litigation or other proceeding is resolved against us, we or our collaborators may be enjoined from developing, manufacturing, selling or importing our drugs without a license from the other party and we may be held liable for significant damages. We may not be able to obtain any required license on commercially acceptable terms or at all.

Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

Risks Relating to Product Manufacturing, Marketing and Sales, and Reliance on Third Parties

Because we have limited manufacturing experience, and no manufacturing facilities or infrastructure, we are dependent on third-party manufacturers to manufacture drug candidates for us. If we cannot rely on third-party manufacturers, we will be required to incur significant costs and devote significant efforts to establish our own manufacturing facilities and capabilities.

We have limited manufacturing experience and no manufacturing facilities, infrastructure or clinical or commercial scale manufacturing capabilities. In order to continue to develop our drug candidates, apply for regulatory approvals, and ultimately commercialize products, we need to develop, contract for or otherwise arrange for the necessary manufacturing capabilities.

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We currently rely upon third parties to produce material for nonclinical and clinical testing purposes and expect to continue to do so in the future. We also expect to rely upon third parties to produce materials that may be required for the commercial production of our products. Our current and anticipated future dependence upon others for the manufacture of our drug candidates may adversely affect our future profit margins and our ability to develop drug candidates and commercialize any drug candidates on a timely and competitive basis. We currently do not have any long term supply contracts.

There are a limited number of manufacturers that operate under the FDA s current Good Manufacturing Practices, or cGMP, regulations capable of manufacturing our drug candidates. As a result, we may have difficulty finding manufacturers for our products with adequate capacity for our needs. If we are unable to arrange for third-party manufacturing of our drug candidates on a timely basis, or to do so on commercially reasonable terms, we may not be able to complete development of our drug candidates or market them.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured drug candidates ourselves, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control;
- the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us;
- the potential that third-party manufacturers will develop know-how owned by such third party in connection with the production of our drug candidates that becomes necessary for the manufacture of our drug candidates; and
- reliance upon third-party manufacturers to assist us in preventing inadvertent disclosure or theft of our proprietary knowledge.

Any contract manufacturers with which we enter into manufacturing arrangements will be subject to ongoing periodic, unannounced inspections by the FDA, or foreign equivalent, and corresponding state and foreign agencies or their designees to ensure compliance with cGMP requirements and other governmental regulations and corresponding foreign standards. For example, one of our contract manufacturers notified us that it had received a cGMP warning letter from the FDA in February 2011. Any failure by our third-party manufacturers to comply with such requirements, regulations or standards could lead to a delay in the conduct of our clinical trials, or a delay in, or failure to obtain, regulatory approval of any of our drug candidates. Such failure could also result in sanctions being imposed, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, product seizures or recalls, imposition of operating restrictions, total or partial suspension of production or distribution, or criminal prosecution.

Additionally, contract manufacturers may not be able to manufacture our drug candidates at a cost or in quantities necessary to make them commercially viable. To date, our third-party manufacturers have met our manufacturing requirements, but we cannot be assured that they will continue to do so. Furthermore, changes in the manufacturing process or procedure, including a change in the location where the drug substance or drug product is manufactured or a change of a third-party manufacturer, may require prior FDA review and approval in accordance with the FDA s cGMP and NDA/BLA regulations. Contract manufacturers may also be subject to comparable foreign requirements. This review may be costly and time-consuming and could delay or prevent the launch of a drug candidate. The FDA or similar foreign regulatory agencies at any time may also implement new standards, or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of products. If we or our contract manufacturers are unable to comply, we or they may be subject to regulatory action, civil actions or penalties.

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We have no experience selling, marketing or distributing products and no internal capability to do so.

If we receive regulatory approval to commence commercial sales of any of our drug candidates, we will face competition with respect to commercial sales, marketing, and distribution. These are areas in which we have no experience. To market any of our drug candidates directly, we would need to develop a marketing and sales force with technical expertise and with supporting distribution capability. In particular, we would need to recruit a large number of experienced marketing and sales personnel. Alternatively, we could engage a pharmaceutical or other healthcare company with an existing distribution system and direct sales force to assist us. However, to the extent we entered into such arrangements, we would be dependent on the efforts of third parties. If we are unable to establish sales and distribution capabilities, whether internally or in reliance on third parties, our business would suffer materially.

If third parties on whom we rely for clinical trials do not perform as contractually required or as we expect, we may not be able to obtain regulatory approval for or commercialize our products and our business may suffer.

We do not have the ability to independently conduct the clinical trials required to obtain regulatory approval for our drug candidates. We depend on independent clinical investigators, contract research organizations, and other third-party service providers in the conduct of the clinical trials of our drug candidates and expect to continue to do so. We contracted with contract research organizations to manage our Phase 1 clinical trials of IMO-2125 in patients with chronic HCV infection and our Phase 1 clinical trials of IMO-3100 in healthy subjects and expect to contract with such organizations for future clinical trials. We rely heavily on these parties for successful execution of our clinical trials, but do not control many aspects of their activities. We are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and foreign regulatory agencies require us to comply with certain standards, commonly referred to as good clinical practices, and applicable regulatory requirements, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of clinical trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule, or at all, or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval, and commercialization of our drug candidates. If we seek to conduct any of these activities ourselves in the future, we will need to recruit appropriately trained personnel and add to our infrastructure.

The commercial success of any drug candidates that we may develop will depend upon the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community.

Any products that we ultimately bring to the market, if they receive marketing approval, may not gain market acceptance by physicians, patients, third-party payors or others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not become profitable. The degree of market acceptance of our drug candidates, if approved for commercial sale, will depend on a number of factors, including:

- the prevalence and severity of any side effects, including any limitations or warnings contained in the product s approved labeling;
- the efficacy and potential advantages over alternative treatments;
- the ability to offer our drug candidates for sale at competitive prices;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;

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the strength of marketing and distribution support and the timing of market introduction of competitive products; and

publicity concerning our products or competing products and treatments.

Even if a potential product displays a favorable efficacy and safety profile, market acceptance of the product will not be known until after it is launched. Our efforts to educate patients, the medical community, and third-party payors on the benefits of our drug candidates may require significant resources and may never be successful. Such efforts to educate the marketplace may require more resources than are required by conventional technologies marketed by our competitors.

If we are unable to obtain adequate reimbursement from third-party payors for any products that we may develop or acceptable prices for those products, our revenues and prospects for profitability will suffer.

Most patients rely on Medicare, Medicaid, private health insurers, and other third-party payors to pay for their medical needs, including any drugs we may market. If third-party payors do not provide adequate coverage or reimbursement for any products that we may develop, our revenues and prospects for profitability will suffer. Congress enacted a limited prescription drug benefit for Medicare recipients in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. While the program established by this statute may increase demand for our products if we were to participate in this program, our prices will be negotiated with drug procurement organizations for Medicare beneficiaries and are likely to be lower than we might otherwise obtain. Non-Medicare third-party drug procurement organizations may also base the price they are willing to pay on the rate paid by drug procurement organizations for Medicare beneficiaries.

A primary trend in the United States healthcare industry is toward cost containment. In addition, in some foreign countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of our drug candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in commercialization of our products. These further clinical trials would require additional time, resources, and expenses. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our prospects for generating revenue, if any, could be adversely affected and our business may suffer.

In March 2010, the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act became law. These health care reform laws are intended to broaden access to health insurance; reduce or constrain the growth of health care spending, especially Medicare spending; enhance remedies against fraud and abuse; add new transparency requirements for health care and health insurance industries; impose new taxes and fees on certain sectors of the health industry; and impose additional health policy reforms. Among the new fees is an annual assessment on makers of branded pharmaceuticals and biologics, under which a company s assessment is based primarily on its share of branded drug sales to federal health care programs. Such fees could affect our future profitability. Although it is too early to determine the effect of the new health care legislation on our future profitability and financial condition, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

Third-party payors are challenging the prices charged for medical products and services, and many third-party payors limit reimbursement for newly-approved health care products. These third-party payors may base their coverage and reimbursement on the coverage and reimbursement rate paid by carriers for Medicare beneficiaries. Furthermore, many such payors are investigating or implementing methods for reducing health care costs, such as the establishment of capitated or prospective payment systems. Cost containment pressures

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have led to an increased emphasis on the use of cost-effective products by health care providers. In particular, third-party payors may limit the indications for which they will reimburse patients who use any products that we may develop. Cost control initiatives could decrease the price we might establish for products that we or our current or future collaborators may develop or sell, which would result in lower product revenues or royalties payable to us.

We face a risk of product liability claims and may not be able to obtain insurance.

Our business exposes us to the risk of product liability claims that is inherent in the manufacturing, testing, and marketing of human therapeutic drugs. We face an inherent risk of product liability exposure related to the testing of our drug candidates in human clinical trials and will face an even greater risk if we commercially sell any products. Regardless of merit or eventual outcome, liability claims and product recalls may result in:

- decreased demand for our drug candidates and products;
- damage to our reputation;
- regulatory investigations that could require costly recalls or product modifications;
- withdrawal of clinical trial participants;
- costs to defend related litigation;
- substantial monetary awards to clinical trial participants or patients, including awards that substantially exceed our product liability insurance, which we would then have to pay using other sources, if available, and would damage our ability to obtain liability insurance at reasonable costs, or at all, in the future;
- loss of revenue;
- the diversion of management s attention away from managing our business; and
- the inability to commercialize any products that we may develop.

Although we have product liability and clinical trial liability insurance that we believe is adequate, this insurance is subject to deductibles and coverage limitations. We may not be able to obtain or maintain adequate protection against potential liabilities. If we are unable to obtain insurance at acceptable cost or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may materially and adversely affect our business and financial position. These liabilities could prevent or interfere with our commercialization efforts.

Risks Relating to an Investment in Our Common Stock

Our corporate governance structure, including provisions in our certificate of incorporation and by-laws and Delaware law, may prevent a change in control or management that stockholders may consider desirable.

Section 203 of the Delaware General Corporation Law and our certificate of incorporation and by-laws contain provisions that might enable our management to resist a takeover of our company or discourage a third party from attempting to take over our company. These provisions include:

a classified board of directors;

limitations on the removal of directors;

limitations on stockholder proposals at meetings of stockholders;

the inability of stockholders to act by written consent or to call special meetings; and

the ability of our board of directors to designate the terms of and issue new series of preferred stock without stockholder approval.

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In addition, Section 203 of the Delaware General Corporation Law imposes restrictions on our ability to engage in business combinations and other specified transactions with significant stockholders. These provisions could have the effect of delaying, deferring or preventing a change in control of us or a change in our management that stockholders may consider favorable or beneficial. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock.

Our stock price has been and may in the future be extremely volatile. In addition, because an active trading market for our common stock has not developed, our investors ability to trade our common stock may be limited. As a result, investors may lose all or a significant portion of their investment.

Our stock price has been volatile. During the period from January 1, 2010 to March 1, 2012, the closing sales price of our common stock ranged from a high of $6.94 per share to a low of $0.97 per share. The stock market has also experienced significant price and volume fluctuations, particularly within the past three years, and the market prices of biotechnology companies in particular have been highly volatile, often for reasons that have been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

- timing and results of nonclinical studies and clinical trials of our drug candidates or those of our competitors;
- the regulatory status of our drug candidates;
- failure of any of our drug candidates, if approved, to achieve commercial success;
- the success of competitive products or technologies;
- regulatory developments in the United States and foreign countries;
- our success in entering into collaborative agreements;
- developments or disputes concerning patents or other proprietary rights;
- the departure of key personnel;
- variations in our financial results or those of companies that are perceived to be similar to us;
- our cash resources;
- the terms of any financing conducted by us;
- changes in the structure of healthcare payment systems;

market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts reports or recommendations; and

general economic, industry, and market conditions.

In addition, our common stock has historically been traded at low volume levels and may continue to trade at low volume levels. As a result, any large purchase or sale of our common stock could have a significant impact on the price of our common stock and it may be difficult for investors to sell our common stock in the market without depressing the market price for the common stock or at all.

As a result of the foregoing, investors may not be able to resell their shares at or above the price they paid for such shares. Investors in our common stock must be willing to bear the risk of fluctuations in the price of our common stock and the risk that the value of their investment in our stock could decline.

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We must meet the NASDAQ Global Market continued listing requirements or we risk delisting, which may decrease our stock price and make it harder for our stockholders to trade our stock.

Our common stock is currently listed on the NASDAQ Global Market and has traded as low as $0.95 per share during the fourth quarter of 2011 and has traded just under $1.20 per share during much of the fourth quarter of 2011 and the first quarter of 2012. We are required to meet specified financial requirements to maintain such listing, one of which is that we maintain a minimum closing price of at least $1.00 per share for our common stock. If we fail to maintain the $1.00 minimum closing price for 30 consecutive business days, we may be at risk of delisting. Upon receipt of a deficiency notice from NASDAQ we have 180 days to attempt to regain compliance, such as through a reverse stock split. If we do not regain compliance during this initial period, we may be eligible for an additional 180 day compliance period. To qualify, we would be required to transfer to the NASDAQ Capital Market, meet the listing requirements for that market (with the exception of the minimum closing price requirement) and present a plan to regain compliance with the $1.00 minimum closing price requirement. However, if it appears to the NASDAQ that we will not be able to cure the deficiency, or if we are otherwise not eligible, our common stock would be subject to delisting. While there is a right to appeal the NASDAQ s determination to delist our common stock, there can be no assurance they would grant our request for continued listing.

There can be no assurance that we will meet the continued listing requirements for the NASDAQ Global Market, or that our common stock will not be delisted from the NASDAQ Global Market in the future. If our common stock is delisted from NASDAQ, it may be eligible to trade on the over-the-counter market, which may be a less liquid market, or on the pink sheets. In such case, our stockholders ability to trade, or obtain quotations of the market value of, shares of our common stock would be severely limited because of lower trading volumes and transaction delays. These factors could contribute to lower prices and larger spreads in the bid and ask prices for our securities. There can be no assurance that our common stock, if delisted from the NASDAQ Global Market, will be listed on a national securities exchange, a national quotation service, the OTC Bulletin Board or the pink sheets. Delisting from NASDAQ, or even the issuance of a notice of potential delisting, would also result in negative publicity, make it more difficult for us to raise additional capital, adversely affect the market liquidity of our common stock, reduce security analysts coverage of us and diminish investor, supplier and employee confidence.

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

None.

Item 2. ***Properties.***

We lease approximately 26,000 square feet of laboratory and office space located in Cambridge, Massachusetts. The lease expires on May 31, 2014, subject to a five-year renewal option exercisable by us. We have specified rights to sublease this facility.

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

None.

Item 4. ***Mine Safety Disclosures.***

Not applicable.

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PART II.

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

Market Information

Our common stock is listed on the NASDAQ Global Market under the symbol IDRA.

The following table sets forth, for the periods indicated, the high and low sales prices per share of our common stock during each of the quarters set forth below as reported on the NASDAQ Global Market. These prices reflect inter-dealer prices without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

	High	Low
2010		
First Quarter	$ 6.33	$ 4.50
Second Quarter	7.32	3.02
Third Quarter	3.88	3.08
Fourth Quarter	3.54	2.35
2011		
First Quarter	$ 3.73	$ 2.34
Second Quarter	2.74	2.00
Third Quarter	2.24	1.02
Fourth Quarter	2.04	.95

As of January 31, 2012, we had approximately 140 common stockholders of record registered on the books of the Company, excluding shares held through banks and brokers.

Dividends

We have never declared or paid cash dividends on our common stock, and we do not expect to pay any cash dividends on our common stock in the foreseeable future.

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Comparative Stock Performance

The following performance graph and related information shall not be deemed soliciting material or to be filed with the SEC, nor shall such information be incorporated by reference into any future filing under the Securities Act of 1933 or Securities Exchange Act of 1934, each as amended, except to the extent that we specifically incorporate it by reference into such filing.

On December 10, 2007, the Company s common stock began trading on the NASDAQ Global Stock Market under the ticker symbol IDRA. Prior to December 10, 2007, the Company s common stock was quoted on the American Stock Exchange under the ticker symbol IDP.

The comparative stock performance graph shown below compares cumulative stockholder return on the Company s common stock from December 31, 2006 through December 31, 2011 with the cumulative total return of the NASDAQ Biotechnology Index and the Russell 2000 Index. This graph assumes an investment of $100 on December 31, 2006 in the Company s common stock and in each of the indices and assumes that dividends are reinvested.

	12/31/06	12/31/07	12/31/08	12/31/09	12/31/10	12/31/11
IDERA PHARMACEUTICALS, INC.	**100.00**	**243.04**	**142.49**	**95.92**	**53.62**	**19.48**
NASDAQ BIOTECHNOLOGY INDEX	**100.00**	**102.49**	**96.54**	**109.94**	**116.84**	**121.41**
RUSSELL 2000 INDEX	**100.00**	**98.43**	**65.18**	**82.89**	**105.14**	**100.75**

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Item 6. ***Selected Financial Data.***

The following selected financial data are derived from our financial statements. The data should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and the financial statements, related notes, and other financial information included herein.

	Year Ended December 31,				
	2011	2010	2009	2008	2007
	(In thousands, except per share data)				
Statement of Operations Data:					
Alliance revenue	$ 53	$ 16,110	$ 34,518	$ 26,450	$ 8,124
Operating expenses:					
Research and development	17,969	24,226	18,570	16,152	13,195
General and administrative	7,939	9,867	8,561	9,798	9,656
Total operating expenses	25,908	34,093	27,131	25,950	22,851
(Loss) income from operations	(25,855)	(17,983)	7,387	500	(14,727)
Other income (expense):					
Decrease in fair value of warrant liability	1,974				
Investment income, net	30	116	145	1,344	1,668
Interest expense		(2)	(3)	(92)	(149)
Foreign currency exchange gain (loss)	75	(94)	(27)	(267)	
(Loss) income before income taxes	(23,776)	(17,963)	7,502	1,485	(13,208)
Income tax benefit			44	24	
Net (loss) income	$ (23,776)	$ (17,963)	$ 7,546	$ 1,509	$ (13,208)
Preferred stock accretion and dividends	4,548				
Net (loss) income applicable to common stockholders	$ (28,324)	$ (17,963)	$ 7,546	$ 1,509	$ (13,208)
Basic net (loss) income per share applicable to common stockholders	$ (1.03)	$ (0.71)	$ 0.32	$ 0.07	$ (0.62)
Diluted net (loss) income per share applicable to common stockholders	$ (1.03)	$ (0.71)	$ 0.31	$ 0.06	$ (0.62)
Shares used in computing basic net (loss) income per common share applicable to common stockholders(1)	27,623	25,139	23,420	22,655	21,221
Shares used in computing diluted net (loss) income per common share applicable to common stockholders(1)	27,623	25,139	24,079	25,331	21,221
Balance Sheet Data:					
Cash, cash equivalents and investments	$ 24,571	$ 34,643	$ 40,207	$ 55,606	$ 23,743
Working capital	18,741	32,100	23,054	32,099	15,908
Total assets	25,595	36,881	47,639	59,400	27,714
Capital lease obligations		8	28	49	70
Note payable					1,143
Redeemable preferred stock	5,921				
Accumulated deficit	(375,418)	(351,642)	(333,679)	(341,225)	(342,734)

Total stockholders equity	12,024	33,101	33,105	22,167	7,719

(1) Computed on the basis described in Note 12 of notes to financial statements appearing elsewhere in this Annual Report on Form 10-K.

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Item 7. ***Management s Discussion and Analysis of Financial Condition and Results of Operations.***

Overview

We are a clinical stage biotechnology company engaged in the discovery and development of novel synthetic DNA- and RNA- based drug candidates. We are developing drug candidates that are designed to modulate immune responses mediated through Toll-like Receptors, or TLRs. TLRs are specific receptors present in immune system cells. We believe that by modulating immune responses mediated through TLRs, we can develop compounds to treat a broad range of diseases. We are also evaluating gene silencing oligonucleotides, or GSOs, which inhibit the production of disease-associated proteins by targeting RNA. We believe that our GSO technology provides us with a platform from which drug candidates for diverse disease indications can be developed.

We are focusing our internal development efforts on TLR-targeted clinical candidates for autoimmune and inflammatory diseases and cancer, and on the advancement of our GSO technology platform. We are seeking to advance our TLR-targeted programs in infectious diseases, respiratory diseases, hematologic oncology, and the use of TLR3 agonists in vaccine adjuvant applications only through partnerships with third parties. We currently are collaborating with Merck Sharp & Dohme Corp. (formerly Merck & Co., Inc.), which is referred to herein as Merck, for the use of agonists of TLRs 7, 8, and 9 as vaccine adjuvants for cancer, infectious diseases, and Alzheimer s disease.

We are developing IMO-3100, an antagonist of TLR7 and TLR9, for the treatment of psoriasis. A TLR antagonist is a compound that blocks activation of an immune response mediated through the targeted TLR. We plan to conduct a Phase 2 clinical trial of IMO-3100 in adult patients with moderate to severe plaque psoriasis over a four-week treatment period. We expect to initiate the trial in the second quarter of 2012. In addition, we have selected IMO-8400, an antagonist of TLRs 7, 8, and 9, for development in the treatment of lupus. We are conducting nonclinical studies of IMO-8400 to support the submission of an Investigational New Drug Application, or IND, for IMO-8400. We expect to submit the IND to the FDA in the fourth quarter of 2012. We have evaluated IMO-3100 and IMO-8400 in preclinical models of several autoimmune diseases including psoriasis, lupus, rheumatoid arthritis, and multiple sclerosis. In these models, treatment with IMO-3100 or IMO-8400 was associated with improvements in a number of disease parameters.

We are developing IMO-2055, an agonist of TLR9, for the treatment of cancer. A TLR agonist is a compound that stimulates an immune response through the targeted TLR. In November 2011, we reacquired rights to develop IMO-2055 from Merck KGaA, Darmstadt, Germany, our former collaborator. We believe that IMO-2055 can be developed for use as an immune modifier in combination with targeted anticancer agents. Recently, we announced favorable data from a Phase 1b clinical trial of IMO-2055 in combination with erlotinib and bevacizumab in patients with advanced non-small cell lung cancer. We anticipate top-line data from a randomized Phase 2 clinical trial of IMO-2055 in combination with cetuximab in second-line patients with squamous cell carcinoma of the head and neck in the second quarter of 2012. We also expect in the second quarter of 2012 top-line data from a Phase 1b clinical trial of IMO-2055 in combination with cetuximab and chemotherapy in patients with advanced colorectal cancer. Cetuximab, erlotinib, and bevacizumab are marketed under the names Erbitux®, Tarceva®, and Avastin®, respectively.

At December 31, 2011, we had an accumulated deficit of $375.4 million. We expect to incur substantial operating losses in future periods. We do not expect to generate significant product revenue, sales-based milestones or royalties until we successfully complete development and obtain marketing approval for drug candidates, either alone or in collaborations with third parties, which we expect will take a number of years. In order to commercialize our drug candidates, we need to complete clinical development and to comply with comprehensive regulatory requirements. In 2012, we expect that our research and development expenses will be comparable to our research and development expenses in 2011.

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Critical Accounting Policies and Estimates

This management s discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, management evaluates its estimates and judgments, including those related to revenue recognition and stock-based compensation. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We regard an accounting estimate or assumption underlying our financial statements as a critical accounting estimate where:

- the nature of the estimate or assumption is material due to the level of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change; and

- the impact of the estimates and assumptions on financial condition or operating performance is material.

Our significant accounting policies are described in Note 2 of the notes to our financial statements appearing elsewhere in this Annual Report on Form 10-K. Not all of these significant policies, however, fit the definition of critical accounting policies and estimates. We believe that our accounting policies relating to revenue recognition, stock-based compensation and Series D redeemable convertible preferred stock and warrants fit the description of critical accounting estimates and judgments.

Revenue Recognition

An important part of our business strategy is to enter into research and development collaborations with biotechnology and pharmaceutical corporations that bring expertise and resources to the potential research and development and commercialization of drugs based on our technology. Under our research and development collaborations, we have generally licensed specified portions of our intellectual property and provided research and development services to the collaborator during the period of continued involvement in the early portion of the collaborations. Our collaborators have generally been responsible for drug development activities initiated after the collaboration is effective. Our collaborators are also generally responsible for any commercialization activities that may be initiated if any of the drug candidates receive marketing approval from the appropriate regulatory authority. The terms of our agreements have included non-refundable license fees, research and development funding, payments based upon achievement of clinical and preclinical development milestones and royalties on product sales.

The following revenue recognition policy incorporates Accounting Standard Update (ASU) No. 2009-13, Multiple-Element Revenue Arrangements and ASU No. 2010-17, Milestone Method of Revenue Recognition both of which we adopted on January 1, 2011. These new accounting standards did not affect revenue that we earned through December 31, 2011. We plan to follow No. 2009-13 prospectively for any arrangements entered into or materially modified after the adoption date. We plan to follow ASU No. 2010-17 prospectively for any future milestones.

When evaluating multiple element arrangements, we consider whether the components of the arrangement represent separate units of accounting based on specified criteria such as whether the deliverable has standalone value to the collaborator. Any fixed or determinable payments that we expect to receive under the arrangement are allocated among the separate units of accounting and the appropriate revenue recognition criteria are applied to each of these separate units. Any item that does not qualify as a separate unit of accounting is combined with other appropriate items and the combined deliverable is treated as a separate unit of accounting.

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Our allocation of fixed or determinable payments to the separate units of accounting is based on the relative-selling-price method, which is based on the following hierarchy used in determining the selling price for each unit of accounting: (1) Vendor specific objective evidence, or VSOE , the price at which the item is regularly sold by the vendor on a standalone basis, is the preferred method; (2) Third-party evidence, or TPE , of vendors selling similar goods to similarly situated customers on a standalone basis if VSOE of selling price of a product or service is not available; and (3) Best estimate of selling price if neither VSOE nor TPE of selling price of a product or service is available.

Our timing of revenue recognition from upfront license fees received under collaboration agreements depends upon the terms of the agreement.

We recognize revenue from reimbursements earned in connection with research and development collaboration agreements as related research and development costs are incurred, and contractual services are performed, provided collectability is reasonably assured. We include amounts contractually owed to us under these research and development collaboration agreements, including any earned but unbilled receivables, in receivables in our balance sheets. Our principal costs under these agreements are generally for our personnel and related expenses of conducting research and development, as well as for research and development performed by outside contractors or consultants or related research and development materials provided by third parties or for clinical trials we conduct on behalf of a collaborator.

For payments that are contingent upon milestone events or achieving a specific result from the research and development efforts, we recognize these milestone payments as revenue in their entirety upon achieving the related milestone provided the milestone meets the criteria specified below. Milestones typically consist of significant events in the development life cycle of the related technology, such as initiating clinical trials, filing for approval with regulatory agencies, and obtaining approvals from regulatory agencies. We recognize revenue from milestone payments received under collaboration agreements in their entirety upon achieving the related milestone, provided that the milestone event is substantive, its achievability was not reasonably assured at the inception of the agreement, the amount attributed to the milestone is reasonable in relation to our performance and to the amounts attributed to the other deliverables in the arrangement and we have no further performance obligations relating to the milestone event. In the event that the agreement provides for payment to be made subsequent to our standard payment terms, we recognize revenue when payment becomes due.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in our balance sheets. We classify amounts that we expect to recognize in the next twelve months as short-term deferred revenue. We classify amounts that we do not expect to recognize within the next twelve months as long-term deferred revenue.

Although we follow detailed guidelines in measuring revenue, certain judgments affect the application of our revenue policy. For example, we record deferred revenue, if any, on our balance sheet as short-term or long-term deferred revenue based on our best estimate of when such amounts would be recognized. However, these estimates are based on our collaboration agreement and our then current operating plan and, if either should change, we could recognize a different amount of deferred revenue over the subsequent twelve-month period.

Our estimate of deferred revenue also reflects our estimate of the periods of our involvement in our collaborations and the estimated periods over which our performance obligations will be completed. In some instances, the timing of satisfying these obligations can be difficult to estimate. Accordingly, our estimates may change in subsequent periods. Such changes to estimates would result in a change in revenue recognition amounts. If these estimates and judgments change over the course of these agreements, it may affect the timing and amount of revenue that we recognize and record in subsequent periods.

Stock-Based Compensation

We recognize all share-based payments to employees as expense in our financial statements based on their fair values. We record compensation expense over an award s vesting period based on the award s fair value at

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the date of grant. Our policy is to charge the fair value of stock options as an expense, adjusted for forfeitures, on a straight-line basis over the vesting period. Prior to December 2011, the vesting of all of our stock options was based on the passage of time and the employees continued service. In December 2011, we granted performance based stock options to purchase 680,000 shares of common stock to employees. Of this amount, options to purchase 170,000 shares will vest immediately upon the achievement of various performance conditions and options to purchase 510,000 shares will begin to vest over a three year service period upon the achievement of the same performance conditions. We recognize expense over the implicit and explicit service periods for awards with performance conditions when we determine the achievement of the performance conditions to be probable.

We use the Black-Scholes option pricing model to estimate the fair value of stock option grants. The Black-Scholes model relies on a number of key assumptions to calculate estimated fair values, including assumptions as to average risk-free interest rate, expected dividend yield, expected life and expected volatility. For the assumed risk-free interest rate, we use the U.S. Treasury security rate with a term equal to the expected life of the option. Our assumed dividend yield of zero is based on the fact that we have never paid cash dividends to common stockholders and have no present intention to pay cash dividends. We use an expected option life based on actual experience. Our assumption for expected volatility is based on the actual stock-price volatility over a period equal to the expected life of the option.

If factors change and we employ different assumptions for estimating stock-based compensation expense in future periods, or if we decide to use a different valuation model, the stock-based compensation expense we recognize in future periods may differ significantly from what we have recorded in the current period and could materially affect our operating income (loss), net income (loss) and earnings (loss) per share. It may also result in a lack of comparability with other companies that use different models, methods and assumptions. The Black-Scholes option pricing model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. These characteristics are not present in our option grants. Although the Black-Scholes option pricing model is widely used, existing valuation models, including the Black-Scholes valuation model, may not provide reliable measures of the fair values of our stock-based compensation.

We recorded charges of $2.7 million, $3.7 million, and $3.1 million in our statements of operations for the years ended December 31, 2011, 2010 and 2009, respectively, for stock compensation expense attributable to share-based payments made to employees and directors. The decrease in stock compensation expense for 2011, as compared to 2010, was primarily due to decreases in the expense associated with employee options granted before 2008 and director options granted before 2009, as well as 2010 stock compensation expense associated with the modification of stock options during 2010 as a result of our adoption of policies on the treatment of options in connection with director or employee retirement. The increase in stock compensation expense for 2010, as compared to 2009, was primarily due to the inclusion of a full year of expense associated with options granted in December 2009 in the 2010 period as compared to the 2009 period which reflected less than one month of expense associated with those options. The modification of stock options during 2010 also contributed to the increase in stock compensation expense during 2010.

Series D Redeemable Convertible Preferred Stock and Warrants

On November 4, 2011, the Company received net proceeds of $9,074,000 from the issuance of the Series D redeemable convertible preferred stock, or Series D Preferred Stock , and warrants. We first assessed these financial instruments under ASC 480, Distinguishing Liabilities from Equity , and determined that neither financial instrument was within the scope of ASC 480. We then assessed these financial instruments under ASC 815, Derivatives and Hedging as follows:

Warrant. We determined that the warrant was a derivative instrument as it contains a price protection feature that causes the warrant to not be considered indexed to the company s own stock and therefore, not qualify for the exemption requirements in ASC 815-40. We recorded the warrant at fair value as of the November 4, 2011 transaction date and will mark the recorded amount to fair value through earnings each quarter. The fair value of the warrant was $3.2 million on the November 4, 2011 transaction date and $1.2 million at December 31, 2011. The $2.0 million decrease in the fair value between November 4, 2011 and December 31, 2011 was recorded as non-operating income in our Statement of Operations.

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Redeemable Convertible Preferred Stock. We determined that the Series D Preferred Stock contained three embedded features: (1) optional redemption by the company; (2) optional redemption by the holder and (3) optional conversion by the holder. We determined that each of the embedded features met the definition of a derivative. We determined that the preferred stock should be considered an equity host for the purposes of assessing the embedded derivatives for potential bifurcation. We noted the following regarding these embedded features:

Optional Redemption by the Company and Optional Redemption by the Holder. We assessed the redemption features under ASC 815-40 to determine if they were eligible for the exemption from derivative accounting. In order to meet the exemption the feature must be indexed to the company s own stock and meet specified criteria for equity classification. We determined that both redemption features met these requirements and were not bifurcated.

Optional conversion by the holder. We determined that the optional conversion by holder feature was clearly and closely related to the preferred stock host. As such the conversion feature did not require bifurcation under ASC 815.

We then assessed the preferred stock under ASC 470, Debt, to determine if there was a beneficial conversion feature (BCF). We determined the value of the BCF by comparing (1) the $6.3 million financing proceeds allocated to the preferred stock, computed by reducing the $9.5 million gross proceeds from the financing by the $3.2 million fair value of the warrant, to (2) the $10.7 million intrinsic value of the common stock that the preferred stock could be converted into on the date of the financing. Based on this comparison, we determined the BCF to be $4.4 million which we recorded in additional paid-in capital.

If the price protection feature is triggered then additional BCF may be recorded.

As the preferred stock is redeemable, we have recorded it in temporary equity . The initial carrying value of the Series D preferred stock was $1.5 million, after discounts for the portion of the financing proceeds allocated to the warrant liability, the BCF and the financing transaction costs. Since the Series D Preferred Stock was immediately convertible, the $4.4 million discount related to the BCF was immediately accreted to preferred dividends in our Statement of Operations, resulting in an increase in the carrying value of the Series D Preferred Stock to $5.9 million. The Series D preferred stock is optionally redeemable by the holder under a fundamental change for $9.1 million plus any accrued but unpaid dividends. Since we have determined that a fundamental change is not currently probable, the remaining discount of $3.2 million will only be accreted to preferred dividends in our Statement of Operations at the time that the redemption becomes probable, if ever.

If we had determined that the preferred stock was a debt host rather than an equity host, the conversion feature would have been bifurcated and accounted for as a derivative. If the conversion feature had been accounted for as a derivative it would have been marked to fair value each quarter with the change in fair value being recorded in other income (expense) in our Statement of Operations. This would have materially affected our net loss available for common stockholders and loss per share.

New Accounting Pronouncements

We adopted Financial Accounting Standards Board, or FASB, Accounting Standard Update No. 2009-13, Multiple-Element Revenue Arrangements (ASU No. 2009-13) on January 1, 2011. ASU No. 2009-13 updates the existing multiple-element revenue arrangements guidance currently included in Accounting Standards Codification No. 605-25 in two ways. The first change relates to the determination of when the individual deliverables included in multiple-element arrangements may be treated as separate units of accounting.

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This is significant since it may result in the requirement to separate more deliverables within an arrangement, ultimately leading to less revenue deferral. The second change modifies the manner in which the transaction consideration is allocated across the separately identified deliverables. Since we are applying ASU No. 2009-13 prospectively to arrangements entered into or materially modified after the adoption date and since there were no new collaborations or material modifications to existing collaborations in the year ended December 31, 2011, the adoption of ASU No. 2009-13 had no effect on our financial position and results of operations through December 31, 2011. The effect that ASU No. 2009-13 may have on our policy for recognizing revenue under any future collaboration agreements will depend upon the terms of those future collaboration agreements, if any.

We adopted FASB Accounting Standard Update No. 2010-17, Milestone Method of Revenue Recognition (ASU No. 2010-17) on January 1, 2011. ASU No. 2010-17 provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. We are applying ASU No. 2010-17 prospectively to arrangements entered into or materially modified after the adoption date. Since we did not earn any milestones during the year ended December 31, 2011, the adoption of ASU No. 2010-17 has had no effect on our financial position and results of operations through December 31, 2011. Since we used a similar method of recognizing milestone revenue prior to adopting ASU No. 2010-17, we do not expect that the adoption of ASU No. 2010-17 will have a significant effect on our policy for recognizing revenue on any milestones that we receive in future periods.

In May 2011, the FASB issued Accounting Standards Update No. 2011-04, Fair Value Measurement (Topic 820) (ASU No. 2011-04), which updates the existing fair value measurement guidance currently included in the Accounting Standards Codification to achieve common fair value measurement and disclosure requirements in United States Generally Accepted Accounting Principles (U.S. GAAP) and International Financial Reporting Standards. ASU 2011-04 is effective on a prospective basis to interim and annual periods beginning after December 15, 2011. We plan to evaluate the effect that ASU 2011-04 may have on our fair value measurement policy.

In June 2011, the FASB issued Accounting Standard Update No. 2011-05, Comprehensive Income (ASU No. 2011-05), which will require companies to present the components of net income and other comprehensive income either as one continuous statement or as two consecutive statements. ASU No. 2011-05 eliminates the option to present components of other comprehensive income as part of the statement of changes in stockholders equity. The update does not change the items which must be reported in other comprehensive income, how such items are measured or when they must be reclassified to net income. ASU No. 2011-05 is effective for interim and annual periods beginning after December 15, 2011. We do not expect ASU No. 2011-05 to have a material impact on our financial position or results of operations.

Results of Operations

Years ended December 31, 2011, 2010 and 2009

Alliance Revenue

Our alliance revenues are comprised primarily of revenue earned under various collaboration and licensing agreements which include license fees, research and development revenues, including reimbursement of internal and third-party expenses, milestones and patent-related reimbursements.

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The following table is a summary of our alliance revenue earned under our collaboration and licensing agreements:

	Year Ended December 31,			Annual Percentage Change	
	2011	2010	2009	2011/2010	2010/2009
		(In millions)			
License fees	$	$ 12.2	$ 22.2	(100)%	(45)%
Research and development		0.1	3.9	(100)%	(97)%
Milestones		3.8	8.3	(100)%	(54)%
Other	0.1		0.1		(100)%
Total alliance revenue	$ 0.1	$ 16.1	$ 34.5	(99)%	(53)%

License Fees. License fees primarily include license fee revenue recognized under our collaborations with Merck KGaA and Merck. License fee revenue during 2010 and 2009 was comprised of amortization of the upfront license fee payments under these collaborations. We recognized license fee revenue ratably over the expected period of our continuing involvement in the collaborations, which has generally represented the estimated research period of the agreement.

The following table is a summary of license fees recognized under our two principal collaborations during 2010 and 2009:

Collaborator	Year Ended December 31, 2010	2009
	(In millions)	
Merck KGaA	$ 7.3	$ 17.1
Merck	4.8	5.0

We received a $40.0 million upfront payment from Merck KGaA in Euros in February 2008 of which we received $39.7 million due to foreign currency exchange rates in effect at the time. We recognized the $40.0 million upfront payment as revenue over the twenty eight-month research term that ended in June 2010. We received a $20.0 million upfront payment from Merck in December 2006. We recognized the $20.0 million upfront payment as revenue over the two-year initial research term and the two-year extension period that ended in December 2010. Since we completed the research portions of these collaborations during 2010, all of the upfront license fee payments were fully amortized by December 2010. Consequently, the amount of license fee revenue that we recognized under the Merck KGaA and Merck collaborations decreased in 2010 and we did not recognize any license fee revenue during 2011.

Research and Development Revenue. Research and development revenues in 2010 and 2009 consisted of reimbursement of us by Merck KGaA of costs incurred by us in connection with clinical trials under our collaboration agreement with Merck KGaA. By March 2010, Merck KGaA had assumed sponsorship of these phase 1b clinical trials of IMO-2055 and the Phase 1 clinical trial in healthy subjects. As a result, we did not incur any such costs or receive any such reimbursements in 2011 and as such did not recognize any research and development revenue in 2011 and research and development revenues decreased by $3.8 million in 2010 compared to 2009.

Milestone Revenue. In 2011, we received no milestones. In 2010, we received $3.8 million as a result of the initiation by Merck KGaA of the Phase 1b clinical trial of IMO-2055 in treatment of patients with squamous cell carcinoma of the head and neck (SCCHN). In 2009, we received $8.3 million in milestone payments as a result of the initiation of a phase 1b clinical trial in patients with colorectal cancer and the initiation by Merck KGaA of a Phase 2 clinical trial of IMO-2055 in patients with recurrent or metastatic SCCHN.

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Other Revenue. Other revenue consisted of reimbursement by licensees of costs associated with patent maintenance.

Research and Development Expenses

Research and development expenses decreased by approximately $6.2 million, or 26%, from $24.2 million in 2010 to $18.0 million in 2011 and increased by approximately $5.6 million, or 30%, from $18.6 million in 2009 to $24.2 million in 2010. In the following table, research and development expense is set forth in five categories which are discussed beneath the table:

	Year Ended December 31,			Annual Percentage Change	
	2011	2010	2009	2011/2010	2010/2009
	(In millions)				
IMO-3100 external development expense	$ 1.7	$ 5.2	$ 0.6	(67)%	767%
IMO-2055 external development expense (cost of regaining rights to cancer program in 2011)	2.4		3.0		(100)%
IMO-2125 external development expense	2.1	7.5	2.2	(72)%	241%
Other drug development expense	4.8	3.9	5.6	23%	(30)%
Basic discovery expense	7.0	7.6	7.2	(8)%	6%
	$ 18.0	$ 24.2	$ 18.6	(26)%	30%

IMO-3100 External Development Expenses. These expenses include external expenses that we have incurred in connection with IMO-3100 since November 2009, when we commenced clinical development of IMO-3100. These external expenses include payments to independent contractors and vendors for drug development activities conducted after the initiation of IMO-3100 clinical development but exclude internal costs such as payroll and overhead expenses. Since November 2009, we have incurred approximately $7.4 million in external development expenses through December 31, 2011, including costs associated with our clinical trials in healthy subjects we initiated in 2010, manufacturing and process development activities related to the production of IMO-3100, and additional nonclinical toxicology studies.

The decrease in IMO-3100 expenses in 2011 as compared to 2010 was primarily attributable to lower costs in 2011 associated with nonclinical safety studies, lower expenses in 2011 associated with the manufacture of additional IMO-3100 drug supplies, and the completion of all patient activities in 2010 with respect to our Phase 1 clinical trials. These reductions in 2011 expenses for IMO-3100 relative to 2010 expenses were partially offset by 2011 costs associated with the preparation for our planned 12-week Phase 2 clinical trial in psoriasis that we subsequently did not initiate.

The increase in IMO-3100 expenses in 2010 as compared to 2009 was primarily due to expenses associated with our Phase 1 clinical trials, we initiated in 2010, nonclinical safety studies including $0.4 million associated with the cancellation of previously scheduled nonclinical chronic toxicology studies during 2010, and the manufacture of additional supplies of IMO-3100 in 2010.

We expect to initiate in the second quarter of 2012 a Phase 2 clinical trial to evaluate IMO-3100 in adult patients with moderate to severe plaque psoriasis over a four-week treatment period. As a result, we expect IMO-3100 expenses to increase in 2012 as compared to 2011.

IMO-2055 External Development Expenses. IMO-2055 is being developed for cancer, excluding vaccines. External development expenses include payments to independent contractors and vendors for drug development activities conducted after the initiation of IMO-2055 clinical development but exclude internal costs such as

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payroll and overhead expenses. Since 2003, when we commenced clinical development of IMO-2055 and through December 31, 2011, we have incurred approximately $19.8 million in external expenses in connection with IMO-2055.

Under our collaboration with Merck KGaA, Merck KGaA was responsible for developing IMO-2055 for the treatment of cancer excluding vaccines. Prior to March 2010, we conducted clinical trials of IMO-2055 under the collaboration and Merck KGaA reimbursed us. As of March 2010, Merck KGaA assumed sponsorship of the one remaining ongoing clinical trial of IMO-2055 for the treatment of cancer and responsibility for all further clinical development of IMO-2055 in the treatment of cancer. As a result of Merck KGaA s assumption of sponsorship of the trials, we did not incur significant expenses for IMO-2055 development in 2010 and 2011, except for costs associated with the termination agreement discussed below.

On November 30, 2011, we entered into an agreement to terminate our collaboration with Merck KGaA and to regain rights for developing TLR9 agonists for the treatment of cancer. In connection with the termination agreement, we agreed to reimburse Merck KGaA for up to 1.8 million ($2.4 million at December 31, 2011) of Merck KGaA s costs for the third party contract research organization that is coordinating the ongoing Phase 2 trial of IMO-2055 in combination with cetuximab, payable in eleven installments commencing on March 1, 2012 including a final payment payable upon Merck KGaA s completion of certain specified activities. We also agreed to pay to Merck KGaA one-time 1.0 million ($1.3 million at December 31, 2011) milestone payments upon occurrence of each of the following milestones: (i) partnering of IMO-2055 with any third party, (ii) initiation of any Phase 2 or Phase 3 clinical trial for IMO-2055 and (iii) regulatory submission of IMO-2055 in any country. The 1.8 million ($2.4 million at December 31, 2011) in installment payments represents the cost of regaining our rights to IMO-2055 and follow-on compounds for use in the treatment of cancer, excluding cancer vaccines, and was recorded as research and development expense in our Statement of Operations for 2011. The milestone payments will be recorded at the time that any milestones are achieved.

IMO-2055 external development expenses decreased by $3.0 million, or 100%, in 2010, as compared to 2009, as a result of Merck KGaA assuming sponsorship of the trials in September 2009 and in March 2010.

We plan to determine our next steps in the development of IMO-2055 after receiving the data from the Phase 2 clinical trial in SCCHN and from the Phase 1b clinical trial in colorectal cancer.

IMO-2125 External Development Expenses. These expenses include external expenses that we have incurred in connection with IMO-2125. These external expenses include payments to independent contractors and vendors for drug development activities conducted after the initiation of IMO-2125 clinical development, but exclude internal costs such as payroll and overhead expenses. We commenced clinical development of IMO-2125 in May 2007 and since then we have incurred approximately $16.3 million in external development expenses through December 31, 2011, including costs associated with our clinical trials manufacturing, process development activities related to the production of IMO-2125, and additional nonclinical toxicology studies.

The decrease in IMO-2125 expenses in 2011 as compared to 2010 was attributable to decreases in costs associated with the Phase 1 clinical trial in null-responder HCV patients that we initiated in September 2007 and the Phase 1 clinical trial in treatment-naive HCV patients that we initiated in October 2009, manufacturing which occurred in 2010 but not in 2011, the preparation in 2010 for a Phase 2 clinical trial of IMO-2125 in non-responder HCV patients that we had planned to conduct, and a decrease in the cost of conducting additional nonclinical safety studies of IMO-2125. The decrease in 2011 was partially offset by costs incurred in the first half of 2011 associated with preparation for the Phase 2 clinical trial of IMO-2125 in treatment-naïve HCV patients that we had planned to initiate in the second quarter of 2011.

The increase in IMO-2125 expenses in 2010 compared to 2009 was primarily due to increased expenses resulting from the two Phase 1 clinical trials, manufacture of additional supplies of IMO-2125 in 2010, conduct of additional nonclinical safety studies of IMO-2125, and the preparation for a Phase 2 clinical trial in non-responder HCV patients.

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In the third quarter of 2011, we determined to discontinue further development of IMO-2125 in the treatment of HCV. As a result, we expect that IMO-2125 external development expenses will be significantly lower in future periods.

Other Drug Development Expenses. These expenses include external expenses associated with preclinical development of identified compounds in anticipation of advancing these compounds into clinical development. In addition, these expenses include internal costs, such as payroll and overhead expenses, associated with preclinical development and products in clinical development. The external expenses associated with preclinical compounds include payments to contract vendors for manufacturing and the related stability studies, preclinical studies, including animal toxicology and pharmacology studies, and professional fees. Expenses associated with products in clinical development include costs associated with our Hepatitis C Clinical Advisory Board and our Autoimmune Disease Scientific Advisory Board.

The increase in other drug development expenses in 2011, as compared to 2010, was primarily due to increases in the cost of nonclinical studies of preclinical compounds, manufacturing expenses and consulting costs. These increases reflect costs associated with preclinical studies to support the planned submission of an IND for IMO-8400 during the fourth quarter of 2012 and were partially offset by lower employee expenses in 2011. The increase in other drug development expenses during 2011 also reflects the cost of obtaining nonclinical and clinical trial data from studies conducted by Novartis of IMO-2134, a TLR9 agonist.

The decrease in other drug development expenses in 2010, as compared to 2009, was primarily due to the inclusion of IMO-3100 expenses incurred after the commencement of clinical development in November 2009 in the IMO-3100 External Development Expense category shown separately above. Prior to November 2009, nonclinical safety and pharmacology study expenses related to IMO-3100 and costs to manufacture IMO-3100 were included in the Other Drug Development Expenses category.

Basic Discovery Expenses. These expenses include our internal and external expenses relating to our discovery efforts with respect to our TLR-targeted programs, including agonists and antagonists of TLRs 3, 7, 8 and 9, TLR antisense, and GSOs. These expenses reflect payments for laboratory supplies, external research, and professional fees, as well as payroll and overhead expenses. The decrease in basic discovery expenses in 2011, as compared to 2010, was primarily due to decreases in the cost of laboratory supplies and employee expenses.

The increase in basic discovery expenses in 2010 from 2009 is primarily attributable to higher employee expenses, including higher stock compensation expense associated with stock options granted after September 30, 2009 and the addition of a Vice President of Biology to our discovery staff in July 2009, and higher allocated facilities costs, offset by a decrease in research supplies related to decreased research conducted under our collaboration agreements and lower external nonclinical research costs.

We do not know if we will be successful in developing any drug candidate from our research and development programs. At this time, without knowing the results of the ongoing Phase 2 clinical trial of IMO-2055 and the planned Phase 2 clinical trial of IMO-3100, and without an established plan for future clinical tests of drug candidates, we cannot reasonably estimate or know the nature, timing, and costs of the efforts that will be necessary to complete the remainder of the development of, or the period, if any, in which material net cash inflows may commence from, any drug candidate from our research and development programs. Moreover, the clinical development of any drug candidate from our research and development programs is subject to numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of unanticipated events arising during clinical development.

General and Administrative Expenses

General and administrative expenses decreased by approximately $2.0 million, or 20%, from $9.9 million in 2010 to $7.9 million in 2011 and increased by approximately $1.3 million, or 15%, from $8.6 million in 2009 to

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$9.9 million in 2010. General and administrative expenses consist primarily of salary expense, stock compensation expense, consulting fees and professional legal fees associated with our patent applications and maintenance, our corporate regulatory filing requirements, our corporate legal matters, and our business development initiatives.

The $2.0 million decrease in general and administrative expenses in 2011, as compared to 2010, was primarily due to decreases in stock based compensation, employee cash compensation expenses and consulting fees associated with business and strategic initiatives in 2011. The decrease in stock compensation expense during 2011 was mainly due to higher recognized expense in 2010 associated with the modification of non-employee director stock options and lower expense recognized in 2011 due to options whose fair value had been fully amortized prior to the end of 2011. These decreases in general and administrative expenses were partially offset by increases in legal costs associated with patent matters in 2011.

The $1.3 million increase in general and administrative expenses from 2009 to 2010 was primarily due to higher stock compensation expense primarily resulting from stock options granted after September 30, 2009 and the modification of stock options during 2010, higher employee expenses, higher legal fees related to patent maintenance and corporate matters, and increased consulting fees associated with business and strategic initiatives, offset, in part, by a decrease in allocated facilities costs.

Decrease in Fair Value of Warrant Liability

We recorded in 2011 a warrant liability of $3.2 million reflecting the fair value of the warrants issued in our November 2011 financing. The warrant was determined to be a derivative instrument since it contains a specified anti-dilution provision that does not meet the indexed to the company s own stock exemption requirements in ASC 815-40. The warrant was classified as a liability, recorded at fair value as of the transaction date and will be marked to fair value through earnings each quarter. The fair value of the warrants decreased to $1.2 million at December 31, 2011 primarily due to a decrease in the price of our common stock. The reduction in the fair value of the warrant liability resulted in the recognition of a $2.0 million gain in other income for 2011. We expect that the fair value of the warrant liability will vary significantly in the future resulting in material non-operating charges and credits in future periods.

Investment Income, net

Investment income decreased by $0.1 million from $0.1 million in 2010 to a negligible amount in 2011. The decrease in investment income in 2011, as compared to 2010, was due to lower average investment balances and lower interest rates in 2011. Investment income amounted to $0.1 million in 2009.

Income Tax Expense

In 2009, we recorded a tax benefit of approximately $44,000 which was primarily related to the carry back of net operating losses to recover 2006 alternative minimum tax as a result of the enactment of the Worker, Homeownership, and Business Assistance Act of 2009.

Foreign Currency Exchange Gain (Loss)

Our foreign currency exchange gain was $0.1 million in 2011 compared to a loss of $(0.1) in 2010 and a negligible amount in 2009. The foreign currency exchange gain during 2011 was primarily due to the impact that the strengthening value of the U.S. dollar had on our Euro-denominated accrued liabilities associated with the cost of re-gaining the rights to our cancer program and our clinical trial obligations. The foreign currency exchange loss during 2010 was primarily due to the impact that fluctuations in U.S. Dollar/Euro currency exchange rates had on the receipt of milestone payments under our Merck KGaA collaboration in the first and third quarters of 2010. In 2009, we earned a milestone for which we had a $4.3 million receivable at

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December 31, 2009. Merck KGaA paid us for this milestone in February 2010 and we received $4.1 million based on foreign exchange rates in effect at the time of payment as a result of the strengthening value of the U.S. dollar. Consequently, we incurred a foreign currency exchange loss of $0.2 million on the milestone payment during the first quarter of 2010. The foreign currency exchange loss during 2010 also reflects the impact that fluctuations in U.S. Dollar/Euro currency exchange rates have on payments under our clinical trial agreements that are denominated in Euros and on the receipt of the milestone payment in the third quarter of 2010 when we earned a $3.8 million milestone for which we received $4.1 million based on foreign exchange rates in effect at the time of payment as a result of the weakening value of the U.S. dollar, resulting in a foreign currency exchange gain of $0.3 million .

Preferred Stock Accretion and Dividends

The $4.5 million in preferred stock accretion and dividends in 2011 consists of $4.4 million related to the beneficial conversion feature of the Series D preferred stock that we have accreted to preferred dividends, as described under Critical Accounting Policies and Estimates, and $0.1 million in dividends payable on shares of our Series D preferred stock.

Net (Loss) Income Applicable to Common Stockholders

As a result of the factors discussed above, our net loss applicable to common stockholders was $28.3 million and $18.0 million for the years ended December 31, 2011 and 2010, respectively. We had net income applicable to common stockholders of $7.5 million for the year ended December 31, 2009. Since January 1, 2001, we have primarily been involved in the development of our TLR pipeline. From January 1, 2001 through December 31, 2011, we incurred losses of $115.2 million. We also incurred net losses of $260.2 million prior to December 31, 2000 during which time we were primarily involved in the development of non-TLR targeted antisense technology. Since our inception, we had an accumulated deficit of $375.4 million through December 31, 2011. We expect to continue to incur substantial operating losses in the future.

Net Operating Loss Carryforwards

As of December 31, 2011, we had cumulative net operating loss carryforwards, or NOLs, of approximately $215.1 million and $65.1 million available to reduce federal and state taxable income which expire through 2031. In addition, we had cumulative federal and state tax credit carryforwards of $5.8 million and $5.0 million, respectively, available to reduce federal and state income taxes, which expire through 2031 and 2026, respectively. The Tax Reform Act of 1986 contains provisions, which limit the amount of NOLs and credit carryforwards that companies may utilize in any one year in the event of cumulative changes in ownership over a three-year period in excess of 50%. We have completed several financings since the effective date of the Tax Reform Act of 1986, which as of December 31, 2011, have resulted in ownership changes in excess of 50% and that will significantly limit our ability to utilize our NOL and tax credit carryforwards. Ownership changes in future periods may place additional limits on our ability to utilize net operating loss and tax credit carryforwards.

Liquidity and Capital Resources

Sources of Liquidity

We require cash to fund our operating expenses and to make capital expenditures. Historically, we have funded our cash requirements primarily through the following:

- equity and debt financing;
- license fees, research funding and milestone payments under collaborative and license agreements;
- interest income; and
- lease financings.

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In August 2010, we raised $15.1 million in gross proceeds from a registered direct offering of our common stock to institutional investors. In the offering, we sold 4,071,005 shares of common stock and warrants to purchase 1,628,402 shares of common stock. The common stock and the warrants were sold in units at a price of $3.71 per unit, with each unit consisting of one share of common stock and warrants to purchase 0.40 shares of common stock. The warrants to purchase common stock have an exercise price of $3.71 per share, are exercisable immediately, and will expire if not exercised on or prior to August 5, 2015. The net proceeds to us from the offering, excluding the proceeds of any future exercise of the warrants, were approximately $14.1 million.

In November 2011, we entered into a Convertible Preferred Stock and Warrant Purchase Agreement, or Purchase Agreement, with Pillar Pharmaceuticals I L.P., or the purchaser, an investment partnership managed by one of our directors. Pursuant to the Purchase Agreement, we issued and sold to the purchaser, for an aggregate purchase price of $9.5 million, 1,124,260 shares of our Series D Preferred Stock convertible, subject to the limitation, into 5,621,300 shares of our common stock, and warrants to purchase 2,810,650 shares of our common stock. The net proceeds to us from the offering, excluding the proceeds of any future exercise of the warrants, were approximately $9.1 million.

The conversion price of the Series D Preferred Stock is subject to adjustment in the event that we issue at any time shares of common stock without consideration or for a consideration per share that is less than $1.46, subject to appropriate adjustment, provided that the Series D Preferred Stock conversion price may not be reduced to a price that is less than $1.46. No holder of the Series D Preferred Stock may convert its shares to the extent such conversion would result in the holder and its affiliates beneficially owning more than 19.99% of the common stock outstanding.

The holder of the Series D Preferred Stock is entitled to receive dividends payable quarterly in arrears at the rate of 7% per annum. Such dividends shall be paid in cash through December 31, 2014 and thereafter in cash or with shares of common stock, as determined by us in our sole discretion, except that we may not pay any dividends to a holder of Series D Preferred Stock in shares of common stock to the extent the issuance of such shares would result in the holder of Series D Preferred Stock and its affiliates beneficially owning more than 19.99% of the common stock outstanding or the combined voting power of our securities outstanding immediately after giving effect to the issuance of such shares of common stock.

After November 4, 2013 and following written notice by us, we may redeem, for a cash payment equal to the $8.1375 original Series D Preferred Stock issue price per share plus any accrued or declared but unpaid dividends thereon, all or a portion of the Series D Preferred Stock if the closing price of our common stock for 20 or more trading days in a period of 30 consecutive trading days is greater than or equal to 200% of the Series D Preferred Stock conversion price. In addition, the holders of shares of Series D Preferred Stock then outstanding are entitled to require us to purchase the shares of Series D Preferred Stock at a price equal to the original Series D Preferred Stock purchase price per share plus all accrued or declared but unpaid dividends thereon upon the occurrence of specified fundamental changes such as mergers, consolidations, business combinations, stock purchases or similar transactions resulting in a person or group unaffiliated with any holder of Series D Preferred Stock owning 66.67% or more our outstanding voting securities of the Company or successor entity.

The warrants have an exercise price of $1.6275 per common share, subject to adjustment therein, and may be exercised at the purchaser s option at any time on or before November 4, 2016. The exercise price of the warrants is subject to adjustment in the event that we issue shares of common stock without consideration or for a price per share that is lower than $1.46, subject to adjustment, provided that the exercise price of the warrants may not be reduced below $1.46. The warrants provide that we will not effect any exercise of the warrants, and the warrants may not be exercised with respect to any portion of the warrants, to the extent that such exercise would result in the purchaser and its affiliates beneficially owning more than 19.99% of the number of shares of common stock outstanding or the combined voting power of our securities outstanding immediately after giving effect to the issuance of shares of common stock issuable upon exercise of the warrant. After November 4, 2013,

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we may redeem the warrants for $0.01 per share of common stock issuable on exercise of the warrants following notice to the purchaser if the closing price of the common stock for 20 or more trading days in a period of 30 consecutive trading days is greater than or equal to $6.51, subject to adjustment.

Under the terms of the Purchase Agreement, we granted the purchaser participation rights in future financings and the purchaser agreed that for so long as the purchaser and its affiliates beneficially own more than 15% of our outstanding common stock, the purchaser and its affiliates will vote any shares held by them in excess of the number of shares equal to 15% of the outstanding common stock (including the shares of common stock issuable upon conversion of the Series D preferred stock) with respect to any matter put to a vote of the holders of common stock in the same manner and percentage as the holders of the common stock (other than the purchaser) vote on such matter. The purchaser has also agreed to be subject to a standstill provision that continues for so long as the purchaser and its affiliates beneficially own more than 15% of the outstanding common stock. In connection with the Purchase Agreement, we also filed a registration statement registering the resale of the shares of common stock issuable upon conversion of the Series D preferred stock and the shares of common stock issuable upon exercise of the warrants.

The net proceeds to us from the offering, excluding the proceeds of any future exercise of the warrants, were approximately $9.1 million.

During 2011, 2010 and 2009, we received total proceeds of $0.1 million, $0.1 million and $0.3 million, respectively, from purchases made under our employee stock purchase plan and stock option exercises.

Under the terms of our collaboration with Merck KGaA, which was terminated in November 2011, we received in February 2008 a $40.0 million upfront license fee in Euros of which we received $39.7 million due to foreign currency exchange rates and approximately $12.1 million in milestone payments and we have been reimbursed $4.5 million for expenses related to the development of IMO-2055.

Under the terms of our collaboration with Merck, Merck paid us a $20.0 million license fee in December 2006 and purchased 1,818,182 shares of our common stock for a price of $5.50 per share for an aggregate purchase price of $10.0 million. Since entering this agreement, we have also received $1.0 million in milestone payments and $3.4 million in research and development payments.

Cash Flows

As of December 31, 2011, we had approximately $24.6 million in cash, cash equivalents and investments, a net decrease of approximately $10.0 million from December 31, 2010. Net cash used in operating activities totaled $19.2 million during 2011, reflecting our $23.8 million net loss for 2011, as adjusted for non-cash income and expenses, including the decrease in the warrant liability, stock-based compensation, the cost of regaining rights to our cancer program, depreciation expense and amortization. It also reflects changes in our prepaid expenses and accounts payable, accrued expenses and other liabilities.

The net cash provided by investing activities during 2011 of $17.6 million reflects the maturity of $18.6 million in available-for-sale securities and a $0.1 million decrease in restricted cash offset by the purchase of approximately $1.0 million of securities during 2011.

The $9.1 million net cash provided by financing activities during 2011 primarily reflects the $9.1 million in net proceeds from the sale of Series D preferred stock and warrants in November 2011 and the proceeds received from employee stock purchases, offset, in part, by payments on our capital leases.

As of December 31, 2010, we had approximately $34.6 million in cash and cash equivalents and investments, a net decrease of approximately $5.6 million from December 31, 2009. Net cash used in operating

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activities totaled $19.6 million during 2010. The $19.6 million reflects our $18.0 million net loss for 2010, as adjusted for non-cash revenue and expenses, including the reduction in deferred revenue associated with the recognition of deferred revenue under our collaboration agreements, stock-based compensation, depreciation and amortization. It also reflects changes in our accounts receivable, prepaid expenses and accounts payable, accrued expenses and other liabilities.

The net cash used in investing activities during 2010 of $3.1 million reflects our purchase of approximately $10.3 million in securities offset by the proceeds of approximately $7.2 million from securities that matured in 2010. The net cash provided by investing activities also reflects a $0.1 million investment in laboratory, office and computer equipment and an increase in available cash of $0.1 million as a result of a reduction in our restricted cash requirements for a security deposit under the terms of the lease for our facility.

The net cash provided by financing activities during 2010 of $14.2 million primarily reflects the $14.1 million in net proceeds from the sale of common stock and warrants in August 2010 and $0.1 million in proceeds received from the exercise of common stock options and employee stock purchases during 2010 offset, in part, by payments under a capital lease.

Net cash used in operating activities totaled $15.6 million during 2009. The $15.6 million reflects our $7.5 million of net income for 2009, as adjusted for non-cash revenue and expenses, including the reduction in deferred revenue associated with the recognition of deferred revenue under our collaboration agreements, stock-based compensation, depreciation and amortization. It also reflects the changes in our accounts receivable, prepaid expenses and accounts payable, accrued expenses and other liabilities.

The net cash used in investing activities during 2009 of $4.3 million reflects our purchase of approximately $14.8 million in securities offset by the proceeds of approximately $10.5 million from securities that matured in 2009. The net cash provided by investing activities also reflects a $0.1 million investment in laboratory, office and computer equipment and an increase in available cash of $0.1 million as a result of a reduction in our restricted cash requirements for a security deposit under the terms of the operating lease for our facility.

The net cash provided by financing activities during 2009 of $0.2 million primarily reflects the $0.3 million in proceeds received from the exercise of common stock options and employee stock purchases during 2009 offset, in part, by $0.1 million used to repurchase 6,615 shares of our common stock and payments under a capital lease.

Funding Requirements

We have incurred operating losses in all fiscal years except 2002, 2008 and 2009, and we had an accumulated deficit of $375.4 million at December 31, 2011. We expect to incur substantial operating losses in future periods. These losses, among other things, have had and will continue to have an adverse effect on our stockholders equity, total assets and working capital.

We have received no revenues from the sale of drugs. To date, almost all of our revenues have been from collaboration and license agreements. We have devoted substantially all of our efforts to research and development, including clinical trials, and we have not completed development of any drugs. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses, whether or when any of our products will become commercially available or when we will become profitable, if at all.

We do not expect to generate significant additional funds internally until we successfully complete development and obtain marketing approval for products, either alone or in collaboration with third parties, which we expect will take a number of years. In addition, we have no committed external sources of funds.

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We had cash and cash equivalents of $24.6 million at December 31, 2011. We believe that our existing cash and cash equivalents will be sufficient to fund our operations at least into the first quarter of 2013 based on the current operating plan, including the Phase 2 clinical trial of IMO-3100 in psoriasis that we plan to initiate in the second quarter of 2012 and the submission of an IND for IMO-8400, which we expect to occur in the fourth quarter of 2012. We will need to raise additional funds in order to operate our business beyond such time.

We will require substantial funds to conduct research and development, including preclinical testing and clinical trials of our drug candidates beyond the first quarter of 2013. We expect to seek additional funding through collaborations, the sale or license of assets or financings of equity or debt securities. We believe that the key factors that will affect our ability to obtain additional funding are:

- the results of our clinical and preclinical development programs;
- developments relating to our existing strategic collaboration with Merck;
- the cost, timing and outcome of regulatory reviews;
- competitive and potentially competitive products and technologies and investors receptivity to our drug candidates and the technology underlying them in light of competitive products and technologies;
- the receptivity of the capital markets to financings by biotechnology companies generally and companies with drug candidates and technologies such as ours specifically; and
- our ability to enter into new strategic collaborations with biotechnology and pharmaceutical companies and the success of such collaborations.

In addition, increases in expenses or delays in clinical development may adversely impact our cash position and require additional funds or further cost reductions. Additional financing may not be available to us when we need it or may not be available to us on favorable terms. We could be required to seek funds through collaborative alliances or others that may require us to relinquish rights to some of our technologies, drug candidates or drugs that we would otherwise pursue on our own. In addition, if we raise additional funds by issuing equity securities, our then existing stockholders will experience dilution. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, and are likely to include rights that are senior to the holders of our common stock. Any additional debt financing or equity that we raise may contain terms, such as liquidation and other preferences, or liens or other restrictions on our assets, which are not favorable to us or our stockholders. The terms of any financing may adversely affect the holdings or the rights of existing stockholders. If we are unable to obtain adequate funding on a timely basis or at all, we may be required to significantly curtail one or more of our discovery or development programs and possibly relinquish rights to portions of our technology or products.

Contractual Obligations

As of December 31, 2011, our contractual commitments were as follows:

		Payments Due by Period			
Contractual Commitment	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**After 5 years**
			(In thousands)		
Operating lease	$ 3,557	$ 1,441	$ 2,116	$	$
License agreements	275	35	70	70	100

Total	$ 3,832	$ 1,476	$ 2,186	$ 70	$ 100

Our only material lease commitment relates to our facility in Cambridge, Massachusetts. Under our antisense technology in-license agreements, we are obligated to make milestone payments upon achieving

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specified milestones and to pay royalties to our licensors. In addition to the minimum license fees shown in the above table, there are contingent milestone and royalty payment obligations that are not included.

The table above does not reflect our obligation to pay dividends to the holders of the Series D convertible preferred stock. Under the terms of the Series D preferred stock, we are obligated to pay dividends quarterly in arrears at the rate of 7%, or $640,000, per annum. Such dividends shall be paid in cash through December 31, 2014 and thereafter we may pay them in cash or with shares of common stock, as determined by us in our sole discretion, except that we may not pay any dividends to a holder of Series D preferred stock in shares of common stock to the extent the issuance of such shares would result in the holder of Series D preferred stock and its affiliates beneficially owning more than 19.99% of our common stock outstanding or the combined voting power of our securities outstanding immediately after giving effect to the issuance of such shares of common stock.

As of December 31, 2011, we had no off balance sheet arrangements. We do not expect to make any material capital expenditures in 2012.

Item 7A. ***Quantitative and Qualitative Disclosures about Market Risk.***

Foreign currency exchange gains and losses may result from amounts to be paid under our Merck KGaA collaboration and termination agreements and payments under our clinical trial agreements that are denominated in Euros. As of December 31, 2011, we had net accrued obligations of 2.2 million, or $2.9 million. All other assets and liabilities are in U.S. dollars, which is our functional currency.

We maintain investments in accordance with our investment policy. The primary objectives of our investment activities are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. Although our investments are subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. We regularly review our investment holdings in light of the then current economic environment. We do not own auction rate securities or derivative financial investment instruments in our investment portfolio.

Based on a hypothetical ten percent adverse movement in interest rates, the potential losses in future earnings, fair value of risk sensitive financial instruments, and cash flows are immaterial, although the actual effects may differ materially from the hypothetical analysis.

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

All financial statements required to be filed hereunder are filed as listed under Item 15(a) of this Annual Report on Form 10-K and are incorporated herein by this reference.

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Quarterly Operating Results (Unaudited)

The following table presents the unaudited statement of operations data for each of the eight quarters in the period ended December 31, 2011. The information for each of these quarters is unaudited, but has been prepared on the same basis as the audited financial statements appearing elsewhere in this Annual Report on Form 10-K. In our opinion, all necessary adjustments, consisting only of normal recurring adjustments, have been made to present fairly the unaudited quarterly results when read in conjunction with the audited financial statements and the notes thereto appearing elsewhere in this document. These operating results are not necessarily indicative of the results of operations that may be expected for any future period.

	Three Months Ended							
	Dec. 31, 2011	Sep. 30, 2011	Jun. 30, 2011	Mar. 31, 2011	Dec. 31, 2010	Sep. 30, 2010	Jun. 30, 2010	Mar. 31, 2010
	(In thousands, except per share data)							
Statement of Operations Data:								
Alliance revenues	$ 8	$ 4	$ 33	$ 8	$ 1,058	$ 5,089	$ 4,386	$ 5,577
Operating expenses:								
Research and development	5,700	3,574	4,142	4,553	4,893	7,786	6,961	4,586
General and administrative	1,539	1,948	2,166	2,286	2,158	2,193	2,784	2,732
Total operating expenses	7,239	5,522	6,308	6,839	7,051	9,979	9,745	7,318
Loss from operations	(7,231)	(5,518)	(6,275)	(6,831)	(5,993)	(4,890)	(5,359)	(1,741)
Decrease in fair value of warrant liability	1,974							
Investment income	2	2	5	21	30	31	29	26
Interest expense					(2)			
Foreign currency exchange gain (loss)	95	27	(12)	(35)	(48)	148	34	(228)
Net loss	$ (5,160)	$ (5,489)	$ (6,282)	$ (6,845)	$ (6,013)	$ (4,711)	$ (5,296)	$ (1,943)
Preferred stock accretion and dividends	4,548							
Net loss applicable to common stockholders	$ (9,708)	$ (5,489)	$ (6,282)	$ (6,845)	$ (6,013)	$ (4,711)	$ (5,296)	$ (1,943)
Basic and diluted net loss per common share applicable to common stockholders	$ (0.35)	$ (0.20)	$ (0.23)	$ (0.25)	$ (0.22)	$ (0.18)	$ (0. 23)	$ (0.08)
Shares used in computing basic and diluted net loss per common share applicable to common stockholders(1)	27,635	27,632	27,619	27,604	27,587	25,980	23,473	23,462

(1) Computed on the basis described in Note 12 of notes to financial statements appearing elsewhere in this Annual Report on Form 10-K.

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

None.

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Item 9A. ***Controls and Procedures.***

Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of December 31, 2011. In designing and evaluating our disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our chief executive officer and chief financial officer concluded that as of December 31, 2011, our disclosure controls and procedures were (1) designed to ensure that material information relating to us is made known to our chief executive officer and chief financial officer by others, particularly during the period in which this report was prepared, and (2) effective, in that they provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms.

Internal Control over Financial Reporting

a) Management s Annual Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, the Company s principal executive and principal financial officers and effected by the Company s board of directors, management and other personnel, 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 and includes those policies and procedures that:

Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;

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

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. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. 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.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2011. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control Integrated Framework.*

Based on this assessment, management believes that, as of December 31, 2011, the Company s internal control over financial reporting is effective based on those criteria.

The Company s independent registered public accounting firm has issued an audit report on the Company s internal control over financial reporting. This report appears below.

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b) Attestation Report of the Independent Registered Public Accounting Firm

Report of Independent Registered Public Accounting Firm

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

We have audited Idera Pharmaceuticals, Inc. s internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Idera 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.

In our opinion, Idera Pharmaceuticals, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2011, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of Idera Pharmaceuticals, Inc. as of December 31, 2011 and 2010, and the related statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2011 of Idera Pharmaceuticals, Inc. and our report dated March 14, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts

March 14, 2012

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c) Changes in Internal Controls over Financial Reporting.
No change in our internal control over financial reporting occurred during the fiscal year ending December 31, 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. ***Other Information.***

None.

PART III.

The response to the Part III items incorporate by reference certain sections of our Proxy Statement for our annual meeting of stockholders to be held on May 23, 2012.

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

We have adopted a written 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. We have posted a current copy of the Code of Business Conduct and Ethics in the Investors Corporate Governance section of our website, which is located at www.iderapharma.com. We intend to satisfy the disclosure requirements under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of our code of business conduct and ethics by posting such information on our website at www.iderapharma.com.

The remainder of the response to this item is contained under the following captions in the 2012 Proxy Statement: Proposal 1 Election of Directors, Section 16(a) Beneficial Ownership Reporting Compliance and Corporate Governance Information, which sections are incorporated herein by reference.

Item 11. ***Executive Compensation.***

The responses to this item are contained in the 2012 Proxy Statement under the captions: Corporate Governance Information Compensation Committee Interlocks and Insider Participation and Executive Compensation, which sections are incorporated herein by reference.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.***
The response to this item is contained in the 2012 Proxy Statement under the caption Security Ownership of Certain Beneficial Owners and Management, which section is incorporated herein by reference.

The disclosures required for securities authorized for issuance under equity compensation plans are contained in the 2012 Proxy Statement under the caption Equity Compensation Plan Information, which section is incorporated herein by reference.

Item 13. ***Certain Relationships and Related Transactions, and Director Independence.***
The response to this item is contained in the 2012 Proxy Statement under the captions Transactions with Related Persons, and Corporate Governance Information Director Independence, which sections are incorporated herein by reference.

Item 14. ***Principal Accountant Fees and Services.***
The response to this item is contained in the 2012 Proxy Statement under the caption Independent Registered Public Accounting Firm Fees, which section is incorporated herein by reference.

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PART IV.

Item 15. ***Exhibits and Financial Statement Schedules.***

(a) (1) *Financial Statements.*

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Statements of Operations for the years ended December 31, 2011, 2010 and 2009	F-4
Statements of Stockholders Equity for the years ended December 31, 2011, 2010 and 2009	F-5
Statements of Cash Flows for the years ended December 31, 2011, 2010 and 2009	F-6
Notes to Financial Statements	F-7

(2) We are not filing any financial statement schedules as part of this Annual Report on Form 10-K because they are not applicable or the required information is included in the financial statements or notes thereto.

(3) The list of Exhibits filed as a part of this Annual Report on Form 10-K is set forth on the Exhibit Index immediately preceding such Exhibits and is incorporated herein by this reference.

(b) The list of Exhibits filed as a part of this Annual Report on Form 10-K is set forth on the Exhibit Index immediately preceding such Exhibits and is incorporated herein by this reference.

(c) None.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on this 14th day of March 2012.

Idera Pharmaceuticals, Inc.

By: /s/ Sudhir Agrawal
Sudhir Agrawal
Chairman, President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Sudhir Agrawal Sudhir Agrawal, D. Phil.	Chairman, President and Chief Executive Officer (Principal Executive Officer)	March 14, 2012
/s/ Louis J. Arcudi III Louis J. Arcudi III	Chief Financial Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)	March 14, 2012
/s/ Youssef El Zein Youssef El Zein	Director	March 14, 2012
/s/ C. Keith Hartley C. Keith Hartley	Director	March 14, 2012
/s/ Robert W. Karr Robert W. Karr, M.D.	Director	March 14, 2012
/s/ Malcolm MacCoss Malcolm MacCoss, Ph.D.	Director	March 14, 2012
/s/ William S. Reardon William S. Reardon, C.P.A.	Director	March 14, 2012
/s/ Eve E. Slater	Director	March 14, 2012

Eve E. Slater, M.D., F.A.C.C.

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IDERA PHARMACEUTICALS, INC.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying balance sheets of Idera Pharmaceuticals, Inc. as of December 31, 2011 and 2010, and the related statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2011. 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 financial position of Idera Pharmaceuticals, Inc. at December 31, 2011 and 2010, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2011, 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), Idera Pharmaceuticals, Inc. s internal control over financial reporting as of December 31, 2011, 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 14, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts

March 14, 2012

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IDERA PHARMACEUTICALS, INC.

BALANCE SHEETS

(In thousands, except per share amounts)	December 31, 2011	December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	$ 24,571	$ 17,008
Short-term investments		17,635
Prepaid expenses and other current assets	255	997
Total current assets	24,826	35,640
Property and equipment, net	458	930
Restricted cash	311	311
Total assets	$ 25,595	$ 36,881
LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,203	$ 1,757
Accrued expenses	4,882	1,783
Total current liabilities	6,085	3,540
Warrant and other liabilities	1,565	240
Total liabilities	7,650	3,780
Commitments and contingencies (Note 9)		
Series D Redeemable Convertible Preferred Stock, $0.01 par value, Authorized, issued and outstanding 1,124 and zero shares at December 31, 2011 and 2010, respectively; Redemption Amount $9,149; Liquidation preference $9,252	5,921	
Non-redeemable Preferred Stock, Common Stock, and Other Stockholders equity:		
Preferred stock, $0.01 par value, Authorized 5,000 shares Series A convertible preferred stock, Designated 1,500 shares, Issued and outstanding 1 share		
Common stock, $0.001 par value, Authorized 70,000 shares Issued and outstanding 27,637 and 27,596 shares at December 31, 2011 and 2010, respectively	28	28
Additional paid-in capital	387,414	384,702
Accumulated deficit	(375,418)	(351,642)
Accumulated other comprehensive income		13
Total stockholders equity	12,024	33,101
Total liabilities, redeemable preferred stock and stockholders equity	$ 25,595	$ 36,881

The accompanying notes are an integral part of these financial statements.

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IDERA PHARMACEUTICALS, INC.

STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)	Years Ended December 31, 2011	2010	2009
Alliance revenue	$ 53	$ 16,110	$ 34,518
Operating expenses:			
Research and development	17,969	24,226	18,570
General and administrative	7,939	9,867	8,561
Total operating expenses	25,908	34,093	27,131
(Loss) income from operations	(25,855)	(17,983)	7,387
Other income (expense):			
Decrease in fair value of warrant liability	1,974		
Investment income, net	30	116	145
Interest expense		(2)	(3)
Foreign currency exchange gain (loss)	75	(94)	(27)
(Loss) income before income taxes	(23,776)	(17,963)	7,502
Income tax benefit			44
Net (loss) income	$ (23,776)	$ (17,963)	$ 7,546
Preferred stock accretion and dividends	4,548		
Net (loss) income applicable to common stockholders	$ (28,324)	$ (17,963)	$ 7,546
Net (loss) income per common share applicable to common stockholders (Note 12):			
Basic	$ (1.03)	$ (0.71)	$ 0.32
Diluted	$ (1.03)	$ (0.71)	$ 0.31
Shares used in computing basic net (loss) income per common share applicable to common stockholders	27,623	25,139	23,420
Shares used in computing diluted net (loss) income per common share applicable to common stockholders	27,623	25,139	24,079

The accompanying notes are an integral part of these financial statements.

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IDERA PHARMACEUTICALS, INC.

STATEMENTS OF STOCKHOLDERS EQUITY

(In thousands)	Common Stock Number of Shares	Common Stock $0.001 Par Value	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive (Loss)/Income	Total Stockholders Equity
Balance, December 31, 2008	23,413	$ 23	$ 363,405	$ (341,225)	$ (36)	$ 22,167
Exercise of common stock options, warrants and employee stock purchases	70		297			297
Issuance of common stock for services	3		17			17
Non-employee stock option expense			9			9
Stock-based compensation			3,093			3,093
Repurchase of common stock	(7)		(41)			(41)
Comprehensive income (loss):						
Unrealized gain on marketable securities					17	17
Net income				7,546		7,546
Total comprehensive income						7,563
Balance, December 31, 2009	23,479	$ 23	$ 366,780	$ (333,679)	$ (19)	$ 33,105
Sale of common stock and warrants, net of issuance costs	4,071	5	14,084			14,089
Exercise of common stock options, warrants and employee stock purchases	44		132			132
Issuance of common stock for services	2		8			8
Non-employee stock option expense			14			14
Stock-based compensation			3,684			3,684
Comprehensive income (loss):						
Unrealized gain on marketable securities					32	32
Net loss				(17,963)		(17,963)
Total comprehensive loss						(17,931)
Balance, December 31, 2010	27,596	$ 28	$ 384,702	$ (351,642)	$ 13	$ 33,101
Exercise of common stock options, warrants and employee stock purchases	26		51			51
Issuance of common stock for services	15		38			38
Non-employee stock option expense			1			1
Stock-based compensation			2,725			2,725
Series D redeemable preferred stock beneficial conversion feature			4,445			4,445
Series D redeemable preferred stock accretion and dividends			(4,548)			(4,548)
Comprehensive income (loss):						
Decrease in unrealized gain on marketable securities					(13)	(13)
Net loss				(23,776)		(23,776)
Total comprehensive loss						(23,789)

Balance, December 31, 2011	27,637	$ 28	$ 387,414	$ (375,418)	$	$ 12,024

The accompanying notes are an integral part of these financial statements.

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IDERA PHARMACEUTICALS, INC.

STATEMENTS OF CASH FLOWS

(In thousands)	Years Ended December 31, 2011	2010	2009
Cash Flows from Operating Activities:			
Net (loss) income	$ (23,776)	$ (17,963)	$ 7,546
Adjustments to reconcile net (loss) income to net cash used in operating activities			
Loss from disposition of assets	1	2	
Non-employee stock option expense	1	14	9
Stock-based compensation	2,725	3,684	3,093
Cost of regaining rights to cancer program	2,423		
Decrease in fair value of warrant liability	(1,974)		
Issuance of common stock for services rendered	38	8	17
Amortization of investment premiums	62	253	40
Depreciation expense	494	546	563
Changes in operating assets and liabilities			
Accounts receivable		4,495	(4,023)
Prepaid expenses and other current assets	640	139	(154)
Accounts payable, accrued expenses, and other liabilities	174	1,431	(383)
Deferred revenue		(12,165)	(22,295)
Net cash used in operating activities	(19,192)	(19,556)	(15,587)
Cash Flows from Investing Activities:			
Purchases of available-for-sale securities	(1,025)	(10,319)	(14,768)
Proceeds from maturity of available-for-sale securities	18,585	7,200	10,450
Decrease in restricted cash	102	103	102
Purchases of property and equipment	(23)	(92)	(126)
Net cash provided by (used in) investing activities	17,639	(3,108)	(4,342)
Cash Flows from Financing Activities:			
Sale of Series D redeemable convertible preferred stock and warrants, net of issuance costs	9,073		
Sale of common stock and warrants, net of issuance costs		14,089	
Proceeds from exercise of common stock options, warrants and employee stock purchases	51	132	297
Repurchase of common stock			(41)
Payments on capital lease	(8)	(20)	(21)
Net cash provided by financing activities	9,116	14,201	235
Net increase (decrease) in cash and cash equivalents	7,563	(8,463)	(19,694)
Cash and cash equivalents, beginning of year	17,008	25,471	45,165
Cash and cash equivalents, end of year	$ 24,571	$ 17,008	$ 25,471

The accompanying notes are an integral part of these financial statements.

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IDERA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS

December 31, 2011

1. Organization

Idera Pharmaceuticals, Inc. (Idera or the Company) is a clinical stage biotechnology company engaged in the discovery and development of novel synthetic DNA- and RNA- based drug candidates. The Company is developing drug candidates that are designed to modulate immune responses mediated through Toll-like Receptors, or TLRs. The Company is also evaluating gene silencing oligonucleotides, or GSOs, which inhibit the production of disease-associated proteins by targeting RNA.

TLRs are specific receptors present in immune system cells. Using a chemistry-based approach, the Company has created synthetic nucleic acid-based compounds that are targeted to TLRs 3, 7, 8, and 9. A TLR agonist is a compound that stimulates an immune response through the targeted TLR. A TLR antagonist is a compound that blocks activation of an immune response through the targeted TLR. Drug candidates are compounds that the Company is developing and that have not been approved for any commercial use.

The Company is focusing its internal development efforts on TLR-targeted clinical candidates for autoimmune and inflammatory diseases and cancer, and on the advancement of its GSO technology platform. The Company is seeking to advance its TLR-targeted programs in infectious diseases, respiratory diseases, hematologic oncology and the use of TLR3 agonists in vaccine adjuvant applications through collaborative alliances with pharmaceutical companies. The Company currently is collaborating with Merck Sharp & Dohme Corp. (formerly Merck & Co., Inc.), which is referred to herein as Merck, for the use of agonists of TLRs 7, 8, and 9 as vaccine adjuvants for cancer, infectious diseases, and Alzheimer s disease.

At December 31, 2011, the Company had an accumulated deficit of $375.4 million. The Company expects to incur substantial operating losses in future periods. The Company does not expect to generate significant funds or product revenue until it successfully completes development and obtains marketing approval for drug candidates, either alone or in collaborations with third parties, which it expects will take a number of years. In order to commercialize its drug candidates, the Company needs to address a number of technological challenges and to comply with comprehensive regulatory requirements.

The Company had cash and cash equivalents of $24.6 million at December 31, 2011. The Company believes that its existing cash and cash equivalents will be sufficient to fund its operations at least into the first quarter of 2013 based on the current operating plan, including a Phase 2 clinical trial of IMO-3100 in psoriasis during this period. The Company will need to raise additional funds in order to operate its business beyond such time. Additional financing may not be available to the Company when it needs it or may not be available on favorable terms.

The Company is subject to a number of risks and uncertainties similar to those of other companies of the same size within the biotechnology industry, such as uncertainty of clinical trial outcomes, uncertainty of additional funding, and history of operating losses.

2. Summary of Significant Accounting Policies

(a) Basis of Presentation

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 reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

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IDERA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(b) Reclassification and Additional Disclosures

Certain amounts in the prior year s financial statements have been reclassified and certain additional disclosures have been made to such financial statements.

(c) Cash, Cash Equivalents and Short-Term Investments

The Company considers all highly liquid investments with maturities of 90 days or less when purchased to be cash equivalents. Cash and cash equivalents at December 31, 2011 and 2010 consisted of cash and money market funds.

Management determines the appropriate classification of marketable securities at the time of purchase. Investments that the Company does not have the positive intent to hold to maturity are classified as available-for-sale and reported at fair market value. Unrealized gains and losses associated with available-for-sale investments are recorded in Accumulated other comprehensive income on the accompanying balance sheets. The amortization of premiums and accretion of discounts, and any realized gains and losses and declines in value judged to be other-than-temporary, and interest and dividends for all available-for-sale securities are included in Investment income, net on the accompanying statements of operations. Investments that the Company intends to hold to maturity are classified as held-to-maturity investments. The Company had no held-to-maturity investments at either December 31, 2011 or 2010. The cost of securities sold is based on the specific identification method.

The Company had no realized gains or losses from available-for-sale securities in 2011, 2010 or 2009. There were no losses or other-than-temporary declines in value included in Investment income, net for any securities for the three years ended December 31, 2011. The Company had no auction rate securities as of December 31, 2011 and 2010.

(d) Restricted Cash

As part of the Company s lease arrangement for its office and laboratory facility (see Note 9(a)), the Company was required to restrict $619,000 of cash for a security deposit. The restricted cash was reduced by a total of approximately $308,000 upon the second, third and fourth anniversaries of the June 2007 lease commencement date. As a result, at December 31, 2011, restricted cash was $311,000. The restricted cash is held in certificates of deposit securing a line of credit for the lessor.

(e) Depreciation and Amortization

Depreciation and amortization are computed using the straight-line method based on the estimated useful lives of the related assets. Laboratory and other equipment are depreciated over three to five years. Leasehold improvements are amortized over the remaining lease term or the related useful life, if shorter.

(f) Revenue Recognition

An important part of the Company s business strategy is to enter into research and development collaborations with biotechnology and pharmaceutical corporations that bring expertise and resources to the potential research and development and commercialization of drugs based on the Company s technology. Under the Company s research and development collaborations, the Company has generally licensed specified portions of its intellectual property and provided research and development services to the collaborator during the period of continued involvement in the early portion of the collaborations. The collaborators have generally been

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IDERA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

responsible for drug development activities initiated after the collaboration is effective. The collaborators are also generally responsible for any commercialization activities that may be initiated if any of the drug candidates receive marketing approval from the appropriate regulatory authority.

When evaluating multiple element arrangements prior to adopting new revenue accounting standards on January 1, 2011, the Company considered whether the components of the arrangement represented separate units of accounting. The Company recognized revenue from non-refundable upfront fees received under collaboration agreements, not specifically tied to a separate earnings process, ratably over the term of the contractual obligation or the Company s estimated continuing involvement under the research collaboration. If the estimated period of continuing involvement was subsequently modified, the period over which the upfront fee was recognized was modified accordingly on a prospective basis. The Company recognized revenue from reimbursements earned in connection with research and development collaboration agreements as related research and development costs were incurred, and contractual services were performed, provided collectability was reasonably assured. For payments that were specifically associated with a separate earnings process, the Company recognized revenue when the specific performance obligation was completed. Performance obligations typically consisted of significant milestones in the development life cycle of the related technology, such as initiating clinical trials, filing for approval with regulatory agencies, and obtaining approvals from regulatory agencies. The Company recognized revenue from milestone payments received under collaboration agreements when earned, provided that the milestone event was substantive, its achievability was not reasonably assured at the inception of the agreement, it had no further performance obligations relating to the event, and collectability was reasonably assured. Amounts received prior to satisfying the above revenue recognition criteria were recorded as deferred revenue in the Company s balance sheet.

Under the Company s existing collaborative arrangements, the Company has received non-refundable license fees, milestone payments, reimbursements of certain internal and external research and development expenses and patent-related expenses. The Company is also entitled to receive royalties on product sales. The Company classifies all of these amounts as revenue in its statement of operations since it considers licensing intellectual property and providing research and development and patent-related services to be part of its central business operations. For the years ended December 31, 2010, and 2009, alliance revenue consisted primarily of revenue recognized under the Merck KGaA and Merck collaborations. Since the Company completed the research portions of these collaborations during 2010, all of the upfront license fee payments were fully amortized and recognized by December 2010. Consequently, the amount of license fee revenue that the Company recognized under the Merck KGaA and Merck collaborations decreased in 2010 and the Company did not recognize any license fee revenue under the Merck KGaA and Merck collaborations during 2011. For the year ended December 31, 2011, alliance revenue consisted primarily of other revenue from the reimbursement by licensees of costs associated with patent maintenance. Alliance revenue for 2011, 2010 and 2009, including revenue recognized under the Company s collaborative arrangements with Merck KGaA and Merck during the 2010 and 2009 periods, was as follows:

	December 31,		
(In thousands)	**2011**	**2010**	**2009**
Merck KGaA	$	$ 11,173	$ 28,558
Merck		4,768	5,826
Total collaboration revenue		15,941	34,384
Other revenue	53	169	134
Total alliance revenue	$ 53	$ 16,110	$ 34,518

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IDERA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

During the years ended December 31, 2010, and 2009, the Company incurred approximately $26,000, and $3,024,000 respectively, in third-party expenses in connection with its collaborative arrangements. The Company did not incur any such expenses in the corresponding 2011 period. These third party expenses are classified as research and development and general and administrative expenses in the Company s statement of operations.

The following revenue recognition policy incorporates Accounting Standard Update (ASU) No. 2009-13, Multiple-Element Revenue Arrangements and ASU No. 2010-17, Milestone Method of Revenue Recognition both of which the Company adopted on January 1, 2011. These new accounting standards did not affect revenue that the Company earned through December 31, 2011. The Company plans to follow No. 2009-13 prospectively for any arrangements entered into or materially modified after the adoption date. The Company plans to follow ASU No. 2010-17 prospectively for any future milestones.

When evaluating multiple element arrangements, the Company considers whether each deliverable of the arrangement represents a separate unit of accounting based on specified criteria such as whether the deliverable has standalone value to the collaborator. Any fixed or determinable payments that the Company expects to receive under the arrangement are allocated among the separate units of accounting and the appropriate revenue recognition criteria are applied to each of these separate units. Any item that does not qualify as a separate unit of accounting is combined with other appropriate items and the combined deliverable is treated as a separate unit of accounting.

The allocation of fixed or determinable payments to the separate units of accounting is based on the relative-selling-price method, which is based on the following hierarchy used in determining the selling price for each unit of accounting: (1) Vendor specific objective evidence, or VSOE , the price at which the item is regularly sold by the vendor on a standalone basis, is the preferred method; (2) Third-party evidence, or TPE , of vendors selling similar goods to similarly situated customers on a standalone basis if VSOE of selling price of a product or service is not available; and (3) Best estimate of selling price if neither VSOE nor TPE of selling price of a product or service is available.

The timing of revenue recognition from upfront license fees received under collaboration agreements depends upon the terms of the agreement.

The Company recognizes revenue from reimbursements earned in connection with research and development collaboration agreements as related research and development costs are incurred, and contractual services are performed, provided collectability is reasonably assured. The Company includes amounts contractually owed to it under these research and development collaboration agreements, including any earned but unbilled receivables, in receivables in its balance sheets. The Company s principal costs under these agreements are generally for its personnel and related expenses of conducting research and development, as well as for research and development performed by outside contractors or consultants or related research and development materials provided by third parties or for clinical trials it conducts on behalf of a collaborator.

For payments that are contingent upon milestone events or achieving a specific result from the research and development efforts, the Company recognizes these milestone payments as revenue in their entirety upon achieving the related milestone provided the milestone meets the criteria specified below. Milestones typically consist of significant events in the development life cycle of the related technology, such as initiating clinical trials, filing for approval with regulatory agencies, and obtaining approvals from regulatory agencies. The Company recognizes revenue from milestone payments received under collaboration agreements in their entirety upon achieving the related milestone, provided that the milestone event is substantive, its achievability was not reasonably assured at the inception of the agreement, the amount attributed to the milestone is reasonable in

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IDERA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

relation to the Company s performance and to the amounts attributed to the other deliverables in the arrangement and the Company has no further performance obligations relating to the milestone event. In the event that the agreement provides for payment to be made subsequent to the Company s standard payment terms, the Company recognizes revenue when payment becomes due.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the Company s balance sheets. The Company classifies amounts that it expects to recognize in the next twelve months as short-term deferred revenue. The Company classifies amounts that it does not expect to recognize within the next twelve months as long-term deferred revenue.

Although the Company follows detailed guidelines in measuring revenue, certain judgments affect the application of its revenue policy. For example, the Company records deferred revenue, if any, on its balance sheet as short-term or long-term deferred revenue based on the Company s best estimate of when such amounts would be recognized. However, these estimates are based on the Company s collaboration agreement and its then current operating plan and, if either should change, the Company could recognize a different amount of deferred revenue over the subsequent twelve-month period.

The Company s estimate of deferred revenue also reflects management s estimate of the periods of its involvement in its collaborations and the estimated periods over which its performance obligations will be completed. In some instances, the timing of satisfying these obligations can be difficult to estimate. Accordingly, the Company s estimates may change in subsequent periods. Such changes to estimates would result in a change in revenue recognition amounts. If these estimates and judgments change over the course of these agreements, it may affect the timing and amount of revenue that the Company recognizes and records in subsequent periods.

Additional information on the Company s collaborative arrangements is included in Note 6.

(g) Financial Instruments

The fair value of the Company s financial instruments is determined and disclosed in accordance with the three-tier fair value hierarchy specified in note 2(n). The Company is required to disclose the estimated fair values of its financial instruments. The Company s financial instruments consist of cash and cash equivalents, investments, receivables and a warrant liability. The estimated fair values of these financial instruments approximate their carrying values as of December 31, 2011 and 2010, respectively. As of December 31, 2011 and 2010, the Company did not have any derivatives, hedging instruments or other similar financial instruments except for the warrant liability discussed in note 2(n) and the Series D redeemable convertible preferred stock, the Series D preferred stock, embedded features discussed in note 7(a).

(h) Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive income (loss) for the years ended December 31, 2011, 2010 and 2009 is comprised of reported net income (loss) and the change in net unrealized gains and losses on investments during each year, which is included in Accumulated other comprehensive income on the accompanying balance sheets.

(i) Net Income (Loss) per Common Share applicable to Common Stockholders

Basic and diluted net loss per common share applicable to common stockholders is computed using the weighted average number of shares of common stock outstanding during the period. In addition, diluted net

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IDERA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

income per common share is calculated to give effect of stock options, convertible preferred stock and warrants (where the effect is not antidilutive) resulting in lower net income per share. The dilutive effect of outstanding stock options, convertible preferred stock and warrants is reflected by the application of the treasury stock method, which assumes that the Company uses the proceeds from the sale of dilutive securities to purchase the Company s common stock at the stock s average closing price during the period. Diluted net loss per common share applicable to common stockholders is the same as basic net loss per common share applicable to common stockholders for the years ended December 31, 2011 and 2010 as the effects of the Company s potential common stock equivalents are antidilutive (see Note 12).

(j) Segment Reporting

The Company views its operations and manages its business as one operating segment. Accordingly, the Company operates in one segment, which is the business of discovering and developing novel therapeutics that modulate immune responses through TLRs. As a result, the financial information disclosed herein represents all of the material financial information related to the Company s principal operating segment. For all of the periods presented, all of the Company s revenues were generated in the United States. As of December 31, 2011 and 2010, all assets were located in the United States.

(k) Stock-Based Compensation

The Company recognizes all share-based payments to employees and directors in the financial statements based on their fair values. The Company records compensation expense over an award s requisite service period, or vesting period, based on the award s fair value at the date of grant. The Company s policy is to charge the fair value of stock options as an expense on a straight-line basis over the vesting period, which is generally four years for employees and three years for directors. Prior to December 2011, the vesting of all of the Company s stock options was based on the passage of time and the employees continued service. In December 2011, the Company granted performance based stock options to purchase 680,000 shares of common stock to employees. Of this amount, options to purchase 170,000 shares will vest immediately upon the achievement of various performance conditions and options to purchase 510,000 shares will begin to vest over a three year service period upon the achievement of the same performance conditions. The Company recognizes expense over the implicit and explicit service periods for awards with performance conditions when the Company determines the achievement of the performance conditions to be probable.

The Company recorded charges of $2,725,000, $3,684,000, and $3,093,000 in its statements of operations for the years ended December 31, 2011, 2010 and 2009, respectively, for stock-based compensation expense attributable to share-based payments made to employees and directors.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model. The following assumptions apply to the options to purchase 1,671,000, 1,087,000, and 1,128,000 shares of common stock granted to employees and directors during the years ended December 31, 2011, 2010 and 2009:

	2011	2010	2009
Average risk free interest rate	1.4%	2.1%	2.5%
Expected dividend yield			
Expected lives (years)	6.3	4.9	5.0
Expected volatility	64%	68%	66%
Weighted average grant date fair value of options granted during the period (per share)	$ 0.75	$ 1.69	$ 3.07
Weighted average exercise price of options granted during the period (per share)	$ 1.26	$ 2.95	$ 5.39

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IDERA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

The expected lives of the options and the expected volatility are based on historical experience. All options granted during the three years ended December 31, 2011 were granted at exercise prices equal to the fair market value of the common stock on the dates of grant.

The Company s adoption of policies with respect to the treatment of stock options in the event of director or employee retirement during 2010 resulted in the modification of stock options by accelerating the vesting of nonvested stock options held by, and by extending the post-retirement period during which stock options may be exercised by, those directors and employees whose retirement qualifies under the terms of the policy. The stock option modifications increased the fair value of those options by $111,000 when modified, of which $6,000 and $104,000 were expensed during 2011 and 2010, respectively.

The intrinsic value of options exercised amounted to $81,000 during 2009. The fair value of options that vested amounted to $2,707,000, $3,915,000, and $3,461,000 during 2011, 2010, and 2009, respectively. As of December 31, 2011, there was $3,884,000 of unrecognized compensation cost related to nonvested stock-based compensation arrangements, which is expected to be recognized over a weighted average period of 2.3 years.

During prior periods, the Company awarded stock options to purchase shares of common stock to persons who were neither employees nor directors. The fair value of the nonvested portion of the non-employee, non-director options is remeasured each quarter. This remeasured fair value is partially expensed each quarter based upon the percentage of the nonvested portion of the option s vesting period that has elapsed to date, less the amount expensed in prior periods. The remeasurement as of December 31st resulted in charges to operations for non-employee, non-director options of $1,000, $14,000, and $9,000 for 2011, 2010, and 2009, respectively.

There was approximately $20,000, $59,000, and $56,000 in compensation expense related to the Company s 1995 Employee Stock Purchase Plan during 2011, 2010 and 2009, respectively. This expense was computed based on the Black-Scholes option pricing model and the following assumptions:

	2011	2010	2009
Average risk free interest rate	0.1%	0.1%	0.2%
Expected dividend yield			
Expected lives (months)	3.0	3.0	3.0
Expected volatility	58%	60%	68%

During 2007, the Company awarded 62,500 shares of restricted common stock to an employee, which vested in three equal annual installments over the three years ended December 31, 2010. The stock s $441,000 fair market value on the date of the grant was amortized over the three-year vesting period. The Company expensed $73,000 and $147,000 of amortization during 2010 and 2009, respectively, with respect to such shares of restricted stock.

(l) Research and Development Expenses

All research and development expenses, including amounts funded by research collaborations, are expensed as incurred. Research and development expenses are comprised of costs incurred in performing research and development activities, including drug development trials and studies, drug manufacturing, laboratory supplies, external research, payroll including stock-based compensation and overhead. In 2009, Merck KGaA sponsored approximately $3.1 million of the Company s research and development activities. In 2009, Merck sponsored approximately $0.8 million of the Company s research and development activities. Sponsored research and development activities were diminutive in 2010 and 2011.

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IDERA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(m) Concentration of Credit Risk

Financial instruments that subject the Company to credit risk primarily consist of cash and cash equivalents and investments. The Company s credit risk is managed by investing its cash and cash equivalents and marketable securities in highly rated money market instruments, certificates of deposit, corporate bonds, and debt securities. Due to these factors, no significant additional credit risk is believed by management to be inherent in the Company s assets. As of December 31, 2011, all of the Company s cash and cash equivalents are held at one financial institution.

(n) Fair Value of Assets and Liabilities

The Company measures fair value at the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date using assumptions that market participants would use in pricing the asset or liability (the inputs) into a three-tier fair value hierarchy. This fair value hierarchy gives the highest priority (Level 1) to quoted prices in active markets for identical assets or liabilities and the lowest priority (Level 3) to unobservable inputs in which little or no market data exists, requiring companies to develop their own assumptions. Observable inputs that do not meet the criteria of Level 1, and include quoted prices for similar assets or liabilities in active markets or quoted prices for identical assets and liabilities in markets that are not active, are categorized as Level 2. Level 3 inputs are those that reflect the Company s estimates about the assumptions market participants would use in pricing the asset or liability, based on the best information available in the circumstances. Valuation techniques for assets and liabilities measured using Level 3 inputs may include unobservable inputs such as projections, estimates and management s interpretation of current market data. These unobservable Level 3 inputs are only utilized to the extent that observable inputs are not available or cost-effective to obtain.

The table below presents the assets and liabilities measured at fair value on a recurring basis at December 31, 2011 and 2010 categorized by the level of inputs used in the valuation of each asset and liability.

(In thousands)	Total	Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
December 31, 2011				
Assets				
Money market funds	$ 24,532	$ 24,532	$	$
Total Assets	$ 24,532	$ 24,532	$	$
Warrant liability	$ 1,178	$	$	$ 1,178
Total Liabilities	$ 1,178	$	$	$ 1,178
December 31, 2010				
Assets				
Money market funds	$ 14,789	$ 14,789	$	$
Other cash equivalents	2,008		2,008	
Short-term investments	17,635	11,216	6,419	

Total Assets	$ 34,432	$ 26,005	$ 8,427	$
Total Liabilities	$	$	$	$

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IDERA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

The Level 1 assets consist of money market funds which are actively traded daily. The Level 2 assets consist of corporate bond investments whose fair value is generally determined from quoted market prices received from pricing services based upon quoted prices from active markets and/or other significant observable market transactions at fair value. Since these prices may not represent actual transactions of identical securities, they are classified as Level 2. Since all investments are classified as available-for-sale securities, any unrealized gains or losses are recorded in accumulated other comprehensive income or loss within stockholders equity on the balance sheet.

In connection with the sale of its Series D preferred stock, the Company issued warrants which contained provisions for anti-dilution protection in the event that the Company issues other equity securities at a price below $1.46 per common share. Because of the potential adjustment to the warrant exercise price that could result from this anti-dilution protection, the warrants do not meet the criteria set forth in ASC 815-40 to be considered indexed to the Company s own stock, as further discussed in Note 7(b). Accordingly, the Company has recorded the fair value of these warrants as a liability. The Company estimated the fair value of these warrants at the issuance date using the Black-Scholes Model as the result was not significantly different than the use of a lattice or binomial model because the anti-dilution protection provision is subject to a floor of $1.46 per share and the initial exercise price is $1.6275. The Company characterized this warrant liability as a level 3 liability because its fair value measurement is based, in part, on significant inputs not observed in the market and reflects the Company s assumptions as to the expected warrant exercise price, the expected volatility of the Company s common stock, the expected dividend yield and the expected percentage of warrants to be exercised.

The warrants will be revalued at the end of each quarter using the Black-Scholes Model and the change in the fair value of the warrants will be recognized in the statement of operations as other income (expense). The following assumptions and other inputs were used to compute the fair value of the warrant liability as of the November 4, 2011 issuance date and as of December 31, 2011:

	November 4, 2011	December 31, 2011
Common stock price	$ 1.92	$ 1.05
Expected warrant exercise price	$ 1.46	$ 1.46
Remaining term of warrant (years)	5.0	4.8
Expected volatility	61%	58%
Average risk free interest rate	0.9%	0.8%
Expected dividend yield		
Expected percentage of warrants to be exercised	100%	100%

The closing price of the Company s common stock is readily determinable since it is publicly traded. The exercise price of the warrant was initially set at $1.6275 and may be adjusted to as low as the $1.46 minimum exercise price per share for diluting effects such as if in specified circumstances the Company sells its common stock at a price below $1.46 per share. Since the Company s common stock has been generally trading below $1.46 since the financing, the Company has used the $1.46 minimum exercise price as an assumption in computing the fair value of the warrant. The remaining term of the warrant is readily determinable from the warrant agreement. The expected volatility is based on the actual stock-price volatility over a period equal to the remaining term of the warrant. The assumed risk-free interest rate is based on the U.S. Treasury security rate with a term equal to the remaining term of the warrant. The assumed dividend yield of zero is based on the fact that the Company has never paid cash dividends to common stockholders and has no present intention to pay cash dividends to common stockholders. The Company assumed that future financings would dilute the warrant holder s ownership in the Company such that the 19.99% ownership limitation would not prevent the warrant holder from exercising all of the warrants during the term of the warrants.

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IDERA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

The fair value of the warrant liability decreased from $3,152,000 at November 4, 2011 to $1,178,000 at December 31, 2011 primarily due to a decrease in the price of the Company s common stock. The reduction in the fair value of the warrant liability resulted in the recognition of a $1,974,000 gain in other income for 2011. The Company expects that the fair value of the warrant liability will vary significantly in the future resulting in material non-operating charges and credits in future periods.

The Company did not elect to measure any other financial assets or liabilities at fair value.

(o) New Accounting Pronouncements

The Company adopted Financial Accounting Standards Board, or FASB, Accounting Standard Update No. 2009-13, Multiple-Element Revenue Arrangements (ASU No. 2009-13) on January 1, 2011. ASU No. 2009-13 updates the existing multiple-element revenue arrangements guidance currently included in Accounting Standards Codification No. 605-25 in two ways. The first change relates to the determination of when the individual deliverables included in multiple-element arrangements may be treated as separate units of accounting. This is significant since it may result in the requirement to separate more deliverables within an arrangement, ultimately leading to less revenue deferral. The second change modifies the manner in which the transaction consideration is allocated across the separately identified deliverables. Since the Company is applying ASU No. 2009-13 prospectively to arrangements entered into or materially modified after the adoption date and since there were no new collaborations or material modifications to existing collaborations in the year ended December 31, 2011, the adoption of ASU No. 2009-13 had no effect on the Company s financial position and results of operations through December 31, 2011. The effect that ASU No. 2009-13 may have on the Company s policy for recognizing revenue under any future collaboration agreements will depend upon the terms of those future collaboration agreements, if any.

The Company adopted FASB Accounting Standard Update No. 2010-17, Milestone Method of Revenue Recognition (ASU No. 2010-17) on January 1, 2011. ASU No. 2010-17 provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. The Company is applying ASU No. 2010-17 prospectively to any milestones earned in the future. Since the Company did not earn any milestones during the year ended December 31, 2011, the adoption of ASU No. 2010-17 has had no effect on the Company s financial position and results of operations through December 31, 2011. Since the Company used a similar method of recognizing milestone revenue prior to adopting ASU No. 2010-17, the Company does not expect that the adoption of ASU No. 2010-17 will have a significant effect on its policy for recognizing revenue on any milestones that it receives in future periods.

In May 2011, the FASB issued Accounting Standards Update No. 2011-04, Fair Value Measurement (Topic 820) (ASU No. 2011-04), which updates the existing fair value measurement guidance currently included in the Accounting Standards Codification to achieve common fair value measurement and disclosure requirements in United States Generally Accepted Accounting Principles (U.S. GAAP) and International Financial Reporting Standards. ASU 2011-04 is effective on a prospective basis to interim and annual periods beginning after December 15, 2011. The Company plans to evaluate the effect that ASU 2011-04 may have on its fair value measurement policy.

In June 2011, the FASB issued Accounting Standard Update No. 2011-05, Comprehensive Income (ASU No. 2011-05), which will require companies to present the components of net income and other comprehensive income either as one continuous statement or as two consecutive statements. ASU No. 2011-05 eliminates the option to present components of other comprehensive income as part of the statement of changes in stockholders

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NOTES TO FINANCIAL STATEMENTS (Continued)

equity. The update does not change the items which must be reported in other comprehensive income, how such items are measured or when they must be reclassified to net income. ASU No. 2011-05 is effective for interim and annual periods beginning after December 15, 2011. The Company does not expect ASU No. 2011-05 to have a material impact on its financial position or results of operations.

3. Marketable Securities

The Company s available-for-sale investments at market value consisted of the following at December 31, 2010:

	December 31, 2010			
	Cost	Gross Unrealized (Losses)	Gross Unrealized Gains	Estimated Fair Value
	(In thousands)			
Agency bonds due in one year or less	$ 3,201	$	$	$ 3,201
Corporate bonds due in one year or less	3,214		4	3,218
U.S. government bonds due in one year or less	11,207		9	11,216
Total investments	$ 17,622	$	$ 13	$ 17,635

There were no available for sale investments at December 31, 2011. See Note 2 (g) and 2(n).

4. Property and Equipment

At December 31, 2011 and 2010, net property and equipment at cost consisted of the following:

	December 31,	
	2011	2010
	(In thousands)	
Leasehold improvements	$ 525	$ 515
Laboratory equipment and other	2,898	2,889
Total property and equipment, at cost	3,423	3,404
Less: Accumulated depreciation	2,965	2,474
Property and equipment, net	$ 458	$ 930

As of December 31, 2011 and 2010, laboratory equipment and other included approximately $79,000 of office equipment financed under capital leases with accumulated depreciation of approximately $72,000 and $56,000, respectively. Depreciation expense, which includes amortization of assets recorded under capital leases, was approximately $494,000, $546,000 and $563,000 in 2011, 2010 and 2009, respectively.

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NOTES TO FINANCIAL STATEMENTS (Continued)

5. Accrued Expenses

At December 31, 2011 and 2010, accrued expenses consisted of the following:

	December 31, 2011	2010
	(In thousands)	
Payroll and related costs	$ 71	$ 164
Clinical and nonclinical trial expenses	2,172	1,204
Cost of regaining rights to cancer program	2,138	
Professional and consulting fees	335	286
Other	166	129
	$ 4,882	$ 1,783

6. Collaboration and License Agreements

(a) Collaboration and License Agreement with Merck KGaA

In December 2007, the Company entered into an exclusive, worldwide license agreement with Merck KGaA to research, develop and commercialize products containing its TLR9 agonists for the treatment of cancer, excluding cancer vaccines, which agreement became effective February 4, 2008. Under the terms of the agreement, the Company granted Merck KGaA worldwide exclusive rights to its lead TLR9 agonists, IMO-2055 and IMO-2125, and to a specified number of novel, follow-on TLR9 agonists to be identified by Merck KGaA and the Company under a research collaboration, for use in the treatment, cure and/or delay of the onset or progression of cancer in humans. Under the terms of the agreement: Merck KGaA paid the Company in February 2008 a $40.0 million upfront license fee in Euros of which $39.7 million was received due to foreign currency exchange rates in effect at that time; Merck KGaA agreed to reimburse future development costs for certain of the Company s IMO-2055 clinical trials for the period in which the Company continued to conduct the trials on behalf of Merck KGaA; Merck KGaA agreed to pay up to 264 million in development, regulatory approval, and commercial success milestone payments if products containing the Company s TLR9 agonist compounds are successfully developed and marketed for treatment, cure and/or delay of the onset or progression of cancer in humans; and Merck KGaA agreed to pay mid single-digit to low double-digit royalties on net sales of products containing the Company s TLR9 agonists that are marketed. Merck KGaA refers to IMO-2055 as EMD 1201081. In February 2009, the agreement was amended so that the Company could initiate and conduct on behalf of Merck KGaA additional clinical trials of EMD 1201081 until such time as Merck KGaA had filed an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) and assumed sponsorship of these trials. Under the amendment, Merck KGaA agreed to reimburse the Company for costs associated with any additional trials that the Company initiated and conducted. Merck KGaA filed an IND and, as of March 2010, Merck KGaA assumed sponsorship of all ongoing clinical trials of EMD 1201081 for the treatment of cancer, and has assumed responsibility for all further clinical development of EMD 1201081 in the treatment of cancer, excluding vaccines.

The Company recognized the $40.0 million upfront payment as revenue over the twenty-eight month term that ended in June 2010, which was the Company s period of continuing involvement under the research collaboration. Through December 31, 2011, the Company has recognized a total of $12.1 million of milestone revenue related to the initiation of clinical trials of EMD 1201081.

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NOTES TO FINANCIAL STATEMENTS (Continued)

In November 2011, the Company and Merck KGaA entered into a termination agreement terminating the license agreement. Under the termination agreement:

- the license agreement was terminated and the Company regained all rights for developing TLR9 agonists for the treatment of cancer, including all rights to IMO-2055 and any follow-on TLR9 agonists;

- Merck KGaA agreed to continue to conduct the ongoing Phase 2 trial of IMO-2055 in combination with Erbitux® and other specified related activities;

- the Company gained rights to the data from the Phase 2 trial of IMO-2055 in combination with Erbitux®, as well as to the data from the Phase 1 trials conducted in other cancer indications;

- the Company agreed to reimburse Merck KGaA a maximum of 1.8 million ($2.4 million at December 31, 2011) of Merck KGaA s costs for the third party contract research organization that is coordinating the ongoing Phase 2 trial of IMO-2055 in combination with Erbitux®, payable in eleven installments comprised of ten monthly installments to be invoiced by Merck KGaA to the Company commencing on March 1, 2012 and a final payment payable by the Company to Merck KGaA upon Merck KGaA s completion of certain specified activities;

- the Company agreed to pay to Merck KGaA one-time 1.0 million ($1.3 million at December 31, 2011) milestone payments upon occurrence of the following milestones: (i) partnering of IMO-2055 between the Company and any third party, (ii) initiation of any Phase 2 or Phase 3 clinical trial for IMO-2055 and (iii) regulatory submission of IMO-2055 in any country; and

- Merck KGaA granted the Company an option to obtain a license to certain manufacturing and formulation know-how owned or developed by Merck KGaA under the License Agreement and to Merck KGaA s IMOxine trademark. If the Company elects to exercise its option to either of these options, the Company has agreed to pay a low single digit royalty on net sales of IMO-2055, with respect to such license(s).

(b) Collaboration and License Agreement with Merck Sharp & Dohme Corp.

In December 2006, the Company entered into an exclusive, worldwide license and research collaboration agreement with Merck to research, develop, and commercialize vaccine products containing the Company s TLR7, 8, and 9 agonists in the fields of cancer, infectious diseases, and Alzheimer s disease. Under the terms of the agreement, the Company granted Merck exclusive rights to a number of the Company s TLR7, 8, and 9 agonists for use in combination with Merck s therapeutic and prophylactic vaccines under development in the fields of cancer, infectious diseases, and Alzheimer s disease. The Company also agreed with Merck to engage in a two-year research collaboration to generate novel agonists targeting TLR7 and TLR8 incorporating both Merck and the Company s chemistry for use in vaccines in the defined fields, which collaboration was extended by Merck for two additional one-year periods. Under the terms of the agreement: Merck paid the Company a $20.0 million upfront license fee; Merck purchased $10.0 million of the Company s common stock at $5.50 per share; and Merck agreed to fund the research and development collaboration. Merck also agreed to pay the Company milestone payments as follows: up to $165.0 million if vaccines containing the Company s TLR9 agonist compounds are successfully developed and marketed in each of the oncology, infectious disease, and Alzheimer s disease fields; up to $260.0 million if vaccines containing the Company s TLR9 agonist compounds are successfully developed and marketed for follow-on indications in the oncology field and if vaccines containing the Company s TLR7 or TLR8 agonists are successfully developed and marketed in each of the oncology, infectious disease, and Alzheimer s disease fields; and if Merck develops and

commercializes additional vaccines using the Company s agonists, the Company would be entitled to receive additional milestone payments. In addition, Merck agreed to pay the Company mid to upper single-digit royalties on net product sales of vaccines using the Company s TLR agonist technology that are developed and marketed.

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The Company recognized the $20.0 million upfront payment as revenue over four years, including the initial two-year research term and the two-year extension period that ended in December 2010, which was the Company s period of continuing involvement under the research collaboration.

In December 2006, in connection with the execution of the license and collaboration agreement, the Company entered into a stock purchase agreement with Merck. Pursuant to such stock purchase agreement, the Company issued and sold to Merck 1,818,182 shares of the Company s common stock for a price of $5.50 per share resulting in aggregate gross proceeds of $10.0 million.

In 2008, the Company recognized $1.0 million of milestone revenue that it received from Merck relating to achieving a preclinical milestone with one of its TLR9 agonists used as an adjuvant in cancer vaccines.

(c) Other License Agreements

The Company has out-licensed and in-licensed therapies related to antisense technology. In 2001 the Company entered into an agreement with Isis Pharmaceuticals, Inc., under which it granted Isis a license, with the right to sublicense, to its antisense chemistry and delivery patents and patent applications; and it retained the right to use these patents and applications in its own drug discovery and development efforts and in collaborations with third parties. During 2001, Isis paid the Company $15.0 million in cash and issued 857,143 shares of its common stock having an aggregate fair market value on the dates on which title to the shares was received of $17.3 million and is required to pay the Company a low to mid double-digit percentage of specified sublicense income it receives from some types of sublicenses of its patents and patent applications. To date, the Company has received $0.3 million in sublicense income from Isis. Also under the agreement, the Company licensed from Isis specified antisense patents and patent applications, principally Isis suite of RNase H patents and patent applications. The Company also paid to Isis $0.7 million and issued 1,005,499 shares of common stock having a fair market value of approximately $1.2 million on the date of issuance for this license and is obligated to pay Isis an annual maintenance fee and low single-digit royalties on net sales of antisense products sold that are covered by Isis s patent rights. The Company has the right to use these patents and patent applications in its drug discovery and development efforts and in some types of third-party collaborations. To date, the Company has only paid Isis annual maintenance fees and has not paid any royalties. The agreement may be terminated for an uncured material breach by either party. The licenses granted under the Isis agreement terminate upon the last to expire of the patents and patent applications licensed under the agreement. The Company may terminate at any time the sublicense by Isis to it of the patents and patent applications.

In addition, the Company is a party to two other license agreements involving the license of its antisense patents and patent applications for oligonucleotide chemistry and delivery and for specific gene targets, under which the Company typically is entitled to receive license fees, sublicensing income, research payments, payments upon achievement of developmental milestones, and royalties on product sales.

The Company s principal in-license related to antisense technology is with University of Massachusetts Medical Center for antisense chemistry and for certain gene targets. Under the terms of the license agreement with University of Massachusetts Medical Center, the Company is the worldwide, exclusive licensee under a number of U.S. issued patents and various patent applications owned by University of Massachusetts Medical Center relating to the chemistry of antisense oligonucleotides and their use. Many of these patents and patent applications have corresponding applications on file or corresponding patents in other major industrial countries. The patents licensed to the Company by University of Massachusetts Medical Center expire at dates ranging from 2006 to 2019. This license expires upon the expiration of the last to expire of the patents covered by the license. Under the agreement, the Company has agreed to pay a low single-digit royalty on net product sales, a

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low double-digit percentage of any sublicense license income received, and a small annual license maintenance fee. The Company has paid approximately $1.7 million to University of Massachusetts Medical Center under this license agreement.

Additionally, the Company has entered into five other royalty-bearing license agreements under which it has acquired rights to antisense related patents, patent applications, and technology. Under all of these in-licenses, the Company is obligated to pay low to mid single-digit royalties on its net sales of products or processes covered by a valid claim of a licensed patent or patent application. Under some of these in-licenses, the Company is required to pay a low double-digit specified percentage of any sublicense income, and all of these in-licenses impose various commercialization, sublicensing, insurance, and other obligations on us, and its failure to comply with these requirements could result in termination of the in-licenses.

7. Series D Redeemable Convertible Preferred Stock and Warrants

The following securities were issued in connection with the Company s November 4, 2011 financing discussed in Note 14.

(a) Redeemable Convertible Preferred Stock

The Series D preferred stock has the rights and preferences set forth in the Certificate of Designations, Preferences and Rights of Series D preferred stock of the Company, or the Certificate of Designations, as summarized below.

Dividends The holders of the Series D preferred stock are entitled to receive dividends payable quarterly in arrears at the rate of 7% per annum. Such dividends shall be paid in cash through December 31, 2014 and thereafter in cash or with shares of common stock, as determined by the Company in its sole discretion, except that the Company may not pay any dividends to a holder of Series D preferred stock in shares of common stock to the extent the issuance of such shares would result in the holder of Series D preferred stock and its affiliates beneficially owning more than 19.99% of (i) the common stock outstanding or (ii) the combined voting power of the securities of the Company outstanding immediately after giving effect to the issuance of such shares of common stock. As of December 31, 2011, the Company had accrued a dividend of $103,000 for payment in January 2012.

Liquidation, Redemption by Holders and Other Events In the event of a liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, after payment or provision for payment of debts and other liabilities of the Company, the holders of the Series D preferred stock then outstanding shall be entitled to be paid out of the assets of the Company available for distribution to its stockholders an amount equal to the greater of (a) the original per share purchase price of the Series D preferred stock ($8.1375 per share) plus all accrued or declared but unpaid dividends thereon and (b) the amount that the holder of Series D preferred stock would be entitled to receive with respect to each share of Series D preferred stock pursuant to such liquidation if all of the outstanding shares of Series D preferred stock had been converted into common stock as of the date immediately prior to the date fixed for determination of stockholders entitled to receive a distribution in such liquidation. Such amount will be paid before any cash distribution may be made or any other assets distributed in respect of junior securities to the holders of any junior securities including, without limitation, common stock and Series A Preferred Stock of the Company. The holders of shares of Series D preferred stock then outstanding shall be entitled to require the Company to purchase such shares of Series D preferred stock at a price equal to the original Series D preferred stock purchase price per share plus all accrued or declared but unpaid dividends thereon upon the occurrence of specified fundamental changes such as mergers, consolidations, business combinations, stock purchases or similar transactions resulting in a person or group unaffiliated with any holder of Series D preferred stock owning 66.67% or more of the outstanding voting securities of the Company or successor entity.

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Conversion Each share of Series D preferred stock is convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and nonassessable shares of common stock as is determined by dividing the Series D preferred stock original issue price by the Series D preferred stock conversion price in effect at the time of conversion. The Series D preferred stock conversion price shall initially be equal to $1.6275 and the Series D preferred stock issue price shall initially be equal to the $8.1375 original purchase price of the Series D preferred stock. Accordingly, each share of Series D preferred stock is initially convertible at the option of the holder into five fully paid and nonassessable shares of the common stock. No holder may convert its shares to the extent such conversion would result in the holder and its affiliates beneficially owning more than 19.99% of the common stock outstanding.

The initial Series D preferred stock conversion price, and the rate at which shares of Series D preferred stock may be converted into shares of common stock, may be subject to adjustment for stock dividends, stock splits and other events, as provided in the Certificate of Designations. In addition, in the event that the Company shall issue at any time shares of common stock without consideration or for a consideration per share that is less than $1.46 (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the common stock), holders of Series D preferred stock will have weighted average anti-dilution protection, except for certain carve outs, with respect to the conversion price of the Series D preferred stock, provided that the Series D preferred stock conversion price may not be reduced to a price that is less than $1.46.

Redemption by Company After November 4, 2013 and following notice the Company may redeem, for cash payment equal to the original Series D preferred stock issue price per share plus any accrued or declared but unpaid dividends thereon, all or a portion of the Series D preferred stock if the closing price of the common stock for 20 or more trading days in a period of 30 consecutive trading days is greater than or equal to 200% of the Series D preferred stock conversion price.

As of November 4, 2011 and December 31, 2011 there were 1,124,260 shares of Series D Preferred Stock authorized, issued and outstanding.

The Series D convertible preferred stock was first assessed under ASC 480, Distinguishing Liabilities from Equity and it was determined that it was not within the scope of ASC 480 so the preferred stock was not considered a liability under ASC 480. The preferred stock was then assessed under ASC 815, Derivatives and Hedging .

The preferred stock contains three embedded features: (1) optional redemption by the Company; (2) optional redemption by the holders and (3) optional conversion by the holders. Each embedded feature meets the definition of a derivative. The Company believes that the Series D preferred stock is an equity host for the purposes of assessing the embedded derivatives for potential bifurcation. The Company noted the following regarding these embedded features:

a. Optional Redemption by the Company and Optional Redemption by the Holder the redemption features were assessed under ASC 815-40 to determine if they were eligible for the exemption from derivative accounting. In order to meet the exemption the feature must be indexed to the company s own stock and meet specified criteria for equity classification. Both redemption features met these requirements and were not bifurcated, or accounted for separately from the preferred stock.

b. Optional Conversion by the Holder the optional conversion by the holder feature was determined to be clearly and closely related to the preferred stock host. As such the conversion feature did not require bifurcation under ASC 815.

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The preferred stock was then assessed under ASC 470, Debt, to determine if there was a beneficial conversion feature (BCF). The BCF compares the carrying value of the preferred stock after the value of any derivatives has been allocated from the proceeds (in this case, the Warrant Liability) to the transaction date value of number of shares that the holder can convert into. The calculation resulted in a BCF of $4,445,000. The BCF was recorded in additional paid-in capital.

If the antidilution protection feature is triggered then additional BCF may be recorded.

The following is a summary of the changes in the Series D preferred stock during 2011 (000s):

Gross proceeds from Series D financing (including $351 paid for the warrants)	$ 9,500
Less allocation of proceeds to:	
fair value of warrants	(3,152)
beneficial conversion feature	(4,445)
transaction costs	(427)
Net proceeds allocated to Series D preferred stock	1,476
Accretion of beneficial conversion feature	4,445
Fair value of Series D preferred stock November 4, 2011	$ 5,921
Fair value of Series D preferred stock December 31, 2011	$ 5,921

Since the Series D preferred stock is redeemable upon events outside the control of the Company, the Company has recorded it in temporary equity. The initial carrying value of the preferred stock was $1,476,000, after discounts for the proceeds allocated to the warrant liability and the BCF, and the recording of the transaction costs. The conversion options of the Series D preferred stock was immediately exercisable, thus the $4,445,000 discount related to the BCF was immediately accreted to preferred dividends, resulting in an increase in the carrying value of the Series D preferred stock to $5,921,000. The Series D preferred stock is redeemable by the holder for the original $9,149,000 purchase price plus unpaid accrued dividends upon a fundamental change, as described above. The Company has determined that the occurrence of a fundamental change is not probable at this time and is not currently accreting the difference between the $5,921,000 fair value of the Series D preferred stock and the redemption value of $9,149,000 purchase price plus unpaid accrued dividends. If the occurrence of a fundamental change becomes probable, the Company will accrete this $3,228,000 difference at that time.

(b) Warrants

The Warrants have an exercise price of $1.6275 per common share (subject to adjustment therein) and may be exercised at the holder s option at any time on or before November 4, 2016. The exercise price of the Warrants is subject to adjustment in the event that the Company issues shares of Common Stock without consideration or for a price per share that is lower than $1.46 (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Common Stock), provided that the exercise price of the Warrants may not be reduced below $1.46. The Warrants provide that the Company shall not effect any exercise of the Warrants, and the Warrants may not be exercised with respect to any portion of the Warrants, to the extent that such exercise would result in the holder and its affiliates beneficially owning more than 19.99% of (i) the number of shares of Common Stock outstanding or (ii) the combined voting power of the securities of the Company outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of the Warrant. After November 4, 2013, the Company may redeem the Warrants for $0.01 per share of Common Stock issuable on exercise of the Warrants

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following notice to the holder if the closing price of the Common Stock for 20 or more trading days in a period of 30 consecutive trading days is greater than or equal to $6.51 (subject to adjustment for stock splits, stock dividends, combinations, recapitalizations, reclassifications, and similar transactions affecting the Common Stock).

The warrants were first assessed under ASC 480, Distinguishing Liabilities from Equity and it was determined that they were not within its scope so the warrants were not considered a liability under ASC 480. The warrants were then assessed under ASC 815, Derivatives and Hedging , and were determined to be a derivative instrument since the price protection features do not meet the indexed to the company s own stock exemption requirements in ASC 815-40. The warrants were recorded at fair value as of the transaction date and are being marked to fair value through earnings at each quarter. See Note 2(n).

8. Non-redeemable Preferred Stock, Common Stock and Other Stockholders Equity

(a) Common Stock

Pursuant to the terms of a unit purchase agreement dated as of May 5, 1998, the Company issued and sold a total of 1,199,684 shares of common stock (the Put Shares) at a price of $16.00 per share. Under the terms of the unit purchase agreement, the initial purchasers (the Put Holders) of the Put Shares have the right (the Put Right) to require the Company to repurchase the Put Shares. The Put Right may not be exercised by any Put Holder unless: 1) the Company liquidates, dissolves or winds up its affairs pursuant to applicable bankruptcy law, whether voluntarily or involuntarily; 2) all of the Company s indebtedness and obligations, including without limitation the indebtedness under the Company s then outstanding notes, has been paid in full; and 3) all rights of the holders of any series or class of capital stock ranking prior and senior to the common stock with respect to liquidation, including without limitation the Series A convertible preferred stock, have been satisfied in full. The Company may terminate the Put Right upon written notice to the Put Holders if the closing sales price of its common stock exceeds $32.00 per share for the twenty consecutive trading days prior to the date of notice of termination. Because the Put Right is not transferable, in the event that a Put Holder has transferred Put Shares since May 5, 1998, the Put Right with respect to those shares has terminated. As a consequence of the Put Right, in the event the Company is liquidated, holders of shares of common stock that do not have Put Rights with respect to such shares may receive smaller distributions per share upon the liquidation than if there were no Put Rights outstanding.

As of December 31, 2011, the Company has repurchased or received documentation of the transfer of 399,950 Put Shares and 35,780 of the Put Shares continued to be held in the name of Put Holders. The Company cannot determine at this time what portion of the Put Rights of the remaining 763,954 Put Shares have terminated.

(b) Warrants

The Company has the following warrants outstanding and exercisable for the purchase of common stock at December 31, 2011:

Expiration Date	Shares	Weighted Average Exercise Price Per share
August 5, 2015	1,628,402	$ 3.71
November 4, 2016	2,810,650	1.63
Total	4,439,052	2.39

See note 7(b).

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(c) Stock Options

Under the 2008 Stock Incentive Plan, the Company may grant options to purchase common stock, stock appreciation rights, restricted stock awards and other forms of stock-based compensation. Stock options generally vest over one to four years, and expire no later than 10 years from the date of grant. A total of 3,700,000 shares of common stock may be issued pursuant to awards granted under the plan subject to reduction in the event that there are any full-value awards, as defined in the plan. The maximum number of shares of common stock with respect to which awards may be granted to any participant under the plan is 500,000 per calendar year. The Compensation Committee of the Board of Directors has the authority to select the employees to whom options are granted and determine the terms of each option, including (i) the number of shares of common stock subject to the option; (ii) when the option becomes exercisable; (iii) the option exercise price, which must be at least 100% (110% in the case of incentive stock options granted to those holding 10% or more of the voting power of the Company) of the fair market value of the common stock as of the date of grant and (iv) the duration of the option, which may not exceed 10 years. Stock options may not be re-priced without shareholder approval. Discretionary awards to non-employee directors are granted and administered by a committee comprised of independent directors. As of December 31, 2011, options to purchase a total of 4,106,113 shares of common stock remained outstanding under the 2008 Stock Incentive Plan. As of December 31, 2011, 1,873,365 shares of common stock remain available for grant under the 2008 Stock Incentive Plan.

The Company is no longer granting stock options or other awards pursuant to the share-based compensation plans that were utilized prior to the approval of the 2008 Stock Incentive Plan. Under these earlier plans, stock options generally vested over three to four years, and expired no later than 10 years from the date of grant. As of December 31, 2011, options to purchase a total of 1,836,925 shares of common stock were outstanding under these plans.

The following table summarizes information related to the outstanding and exercisable options during 2011 (in thousands, except per share amounts and years):

	Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2010	5,395	$ 6.42		
Granted	1,671	1.26		
Exercised				
Forfeited	(188)	3.20		
Expired	(935)	6.48		
Outstanding at December 31, 2011	5,943	4.96	7.54	$
Exercisable at December 31, 2011	3,030	7.16	5.94	
Total exercisable or expected to vest	5,655	5.08	7.46	

(d) Employee Stock Purchase Plan

The 1995 Employee Stock Purchase Plan (the Stock Purchase Plan) was adopted in October 1995 and amended in June 2003 and June 2008. Under the Stock Purchase Plan, up to 250,000 shares of common stock may be issued to participating employees of the Company or its subsidiaries. Participation is limited to employees that would not own 5% or more of the total combined voting power or value of the stock of the Company after the grant.

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NOTES TO FINANCIAL STATEMENTS (Continued)

Under the Stock Purchase Plan, on the first day of a designated payroll deduction period, the Offering Period , the Company will grant to each eligible employee who has elected to participate in the Stock Purchase Plan an option to purchase shares of common stock as follows: the employee may authorize an amount, a whole percentage from 1% to 10% of such employee s regular pay, to be deducted by the Company from such pay during the Offering Period. On the last day of the Offering Period, the employee is deemed to have exercised the option, at the option exercise price, to the extent of accumulated payroll deductions. Under the terms of the Stock Purchase Plan, the option price is an amount equal to 85% of the fair market value per share of the common stock on either the first day or the last day of the Offering Period, whichever is lower. In no event may an employee purchase in any one Offering Period a number of shares that is more than 15% of the employee s annualized base pay divided by 85% of the market value of a share of common stock on the commencement date of the Offering Period. The Compensation Committee may, in its discretion, choose an Offering Period of 12 months or less for each of the Offerings and choose a different Offering Period for each Offering.

Offering periods are three months in duration and commence on March 1, June 1, September 1, and December 1. In 2011, 2010, and 2009, the Company issued 26,155, 43,496, and 28,074 shares of common stock, respectively, under the Stock Purchase Plan.

(e) Preferred Stock

The Restated Certificate of Incorporation of the Company permits its Board of Directors to issue up to 5,000,000 shares of preferred stock, par value $0.01 per share, in one or more series, to designate the number of shares constituting such series, and fix by resolution, the powers, privileges, preferences and relative, optional or special rights thereof, including liquidation preferences and dividends, and conversion and redemption rights of each such series. The Company has designated 1,500,000 shares as Series A convertible preferred stock and 1,124,260 shares of Series D redeemable convertible preferred stock (see Note 7). As of December 31, 2011 and 2010, there were 655 shares of Series A convertible preferred stock outstanding.

(f) Series A Convertible Preferred Stock

The dividends on the Series A convertible preferred stock are payable semi-annually in arrears at the rate of 1% per annum, at the election of the Company, either in cash or additional duly authorized, fully paid and nonassessable shares of Series A preferred stock. The Company paid dividends in stock until 2004 when it elected to pay in cash. In the event of liquidation, dissolution or winding up of the Company, after payment of debts and other liabilities of the Company, the holders of the Series A convertible preferred stock then outstanding will be entitled to a distribution of $1 per share out of any assets available to shareholders. The Series A preferred stock is non-voting. All remaining shares of Series A preferred stock rank as to payment upon the occurrence of any liquidation event senior to the common stock. Shares of Series A preferred stock are convertible, in whole or in part, at the option of the holder into fully paid and nonassessable shares of common stock at $34.00 per share, subject to adjustment.

9. Commitments and Contingencies

(a) Lease Commitments

In June 2007, the Company relocated its operations to a newly leased facility with a lease term through May 31, 2014, with one five-year renewal option exercisable by the Company. During 2011, 2010 and 2009, rent expense, including real estate taxes, was $1,582,000, $1,531,000, and $1,467,000, respectively. As part of the lease, the Company is required to restrict approximately $311,000 of cash for a security deposit as of

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IDERA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

December 31, 2011. The lease is classified as an operating lease. Future minimum commitments as of December 31, 2011 under the Company s lease agreement are approximately:

December 31,	Operating Lease (In thousands)
2012	$ 1,441
2013	1,488
2014	628
	$ 3,557

(b) External Collaborations

The Company is a party to six royalty-bearing license agreements under which it has acquired rights to antisense related patents, patent applications, and technology. Each of these in-licenses automatically terminates upon the expiration of the last to expire patent included in the license. The Company has annual minimum payments due under these agreements of $35,000.

(c) Contract Obligations

The Company has an employment agreement, which expires October 2014, with its chairman, president and chief executive officer. As of December 31, 2011, future minimum commitments under this agreement are approximately $549,000 for each of the years ended December 31, 2012 and 2013, and $440,000 for the year ended December 31, 2014.

(d) Related-Party Transactions

In November, 2011, the Company entered into a Convertible Preferred Stock and Warrant Purchase Agreement with Pillar Pharmaceuticals I L.P., or Pillar, an investment partnership managed by one of the Company s directors and significant shareholders which is described in Note 14.

The Company paid certain directors consulting fees of approximately $32,000, $53,000 and $16,000 in 2011, 2010 and 2009, respectively. The Company issued common stock in lieu of Director board and committee fees of approximately $38,000, $6,000, and $7,000 during 2011, 2010 and 2009, respectively.

10. Income Taxes

Subject to the limitations described below, at December 31, 2011, the Company had cumulative net operating loss carryforwards (NOLs) of approximately $215.1 million and $65.1 million available to reduce federal and state taxable income which expire through 2031. In addition, the Company had cumulative federal and state tax credit carryforwards of $5.8 million and $5.0 million, respectively, available to reduce federal and state income taxes which expire through 2031 and 2026, respectively. The NOLs include approximately $1.9 million of deductions related to the exercise of stock options subsequent to the adoption of Accounting Standards Codification (ASC) 718 Stock Compensation. This amount represents an excess tax benefit as defined under ASC 718 and has not been included in the gross deferred tax asset reflected for NOLs.

The Tax Reform Act of 1986 contains provisions, which limit the amount of net operating loss and tax credit carryforwards that companies may utilize in any one year in the event of cumulative changes in ownership over a

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IDERA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

three-year period in excess of 50%. The Company has completed several financings since the effective date of the Tax Reform Act of 1986, which as of December 31, 2011, have resulted in ownership changes in excess of 50%, and that will significantly limit the Company s ability to utilize its NOL and tax credit carryforwards. The Company has not prepared an analysis to determine the effect of the ownership change limitation on its ability to utilize its net operating loss and tax credit carryforwards as of December 31, 2011. Ownership changes in future periods may place additional limits on the Company s ability to utilize NOLs and tax credit carryforwards.

As of December 31, 2011 and 2010, the components of the deferred tax assets are approximately as follows:

	2011	2010
	(In thousands)	
Operating loss carryforwards	$ 75,817	$ 83,040
Tax credit carryforwards	9,163	8,844
Other	4,844	3,292
	89,824	95,176
Valuation allowance	(89,824)	(95,176)
	$	$

The Company has provided a valuation allowance for its deferred tax asset due to the uncertainty surrounding the ability to realize this asset. The decreases in the operating loss carryforward deferred tax asset and the valuation allowance in the current year is primarily attributable to the expiration of NOLs. The increase in other deferred tax assets is due to the inclusion, in the 2011 Statement of Operations, of non-statutory stock option compensation expense and the cost of regaining rights for developing TLR9 agonists for the treatment of cancer.

The difference between the 34% U.S. federal corporate tax rate and the Company s effective tax rate is as follows for the years ended December 31, 2011, 2010 and 2009:

	2011	2010	2009
Expected federal income tax rate	(34.0)%	(34.0)%	34.0%
Expiring credits and NOLs	66.3	74.2	67.3
Change in valuation allowance	(22.5)	(34.1)	(111.4)
Federal and state credits	(3.3)	(6.4)	(11.6)
State income taxes, net of federal benefit	(5.4)	(4.8)	6.3
Permanent differences	(1.0)	2.6	5.8
State rate change		0.3	6.4
Other	(0.1)	2.2	2.6
Effective tax rate	0.0%	0.0%	(0.6)%

The Company applies ASC 740-10 *Accounting for Uncertainty in Income Taxes, an interpretation of ASC 740*. ASC 740-10 clarifies the accounting for uncertainty in income taxes recognized in financial statements and requires the impact of a tax position to be recognized in the financial statements if that position is more likely than not of being sustained by the taxing authority. The Company had no unrecognized tax benefits resulting from uncertain tax positions at December 31, 2011 and 2010.

The Company has not, as of yet, conducted a study of its research and development credit carryforwards. Such a study might result in an adjustment to the Company s research and development credit carryforwards,

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IDERA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position under ASC 740-10. A full valuation allowance has been provided against the Company s research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the balance sheet or statement of operations if an adjustment was required.

The Company files income tax returns in the U.S. federal and Massachusetts jurisdictions. The Company is no longer subject to tax examinations for years before 2008, except to the extent that it utilizes NOLs or tax credit carryforwards that originated before 2008. The Company does not believe there will be any material changes in its unrecognized tax positions over the next 12 months. The Company has not incurred any interest or penalties. In the event that the Company is assessed interest or penalties at some point in the future, they will be classified in the financial statements as general and administrative expense.

11. Employee Benefit Plan

The Company has an employee benefit plan under Section 401(k) of the Internal Revenue Code. The plan allows employees to make contributions up to a specified percentage of their compensation. Under the plan, the Company matches a portion of the employees contributions up to a defined maximum. The Company is currently contributing up to 3% of employee base salary, by matching 50% of the first 6% of annual base salary contributed by each employee. Approximately $132,000, $139,000, and $130,000 of 401(k) benefits were charged to operating expenses during 2011, 2010 and 2009, respectively.

12. Net Loss per Common Share Applicable to Common Stockholders

For the years ended December 31, 2011 and 2010, basic and diluted net loss per common share applicable to common stockholders is computed using the weighted average number of shares of common stock outstanding during the period. Diluted net loss per common share applicable to common stockholders is the same as basic net loss per common share applicable to common stockholders as the effects of the Company s potential common stock equivalents are antidilutive. Total antidilutive securities were 16,005,000 and 9,491,000 at December 31, 2011 and 2010, respectively, and consist of stock options, preferred stock and warrants.

For the year ended December 31, 2011, net loss per common share applicable to common stockholders reflects $4.5 million in preferred stock accretion and dividends, including $4.4 million related to the beneficial conversion feature of the Series D preferred stock that has been accreted to preferred dividends.

13. Supplemental Disclosure of Cash Flow Information

Supplemental disclosure of cash flow information for the periods presented is as follows:

	Year Ended December 31,		
	2011	2010	2009
		(In thousands)	
Supplemental disclosure of cash flow information:			
Cash paid for income taxes	$	$	$ 220
Supplemental disclosure of non cash financing and investing activities:			
Accretion of Series D redeemable preferred stock beneficial conversion feature	$ 4,445	$	$

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IDERA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

14. Financings

In November, 2011, the Company entered into a Convertible Preferred Stock and Warrant Purchase Agreement, or Purchase Agreement, with Pillar Pharmaceuticals I L.P., or Pillar, an investment partnership managed by one of the Company s directors. Pursuant to the Purchase Agreement, the Company issued and sold to Pillar, for an aggregate purchase price of $9.5 million, 1,124,260 shares of its Series D convertible preferred stock, par value $0.01 per share, or its Series D preferred stock, convertible into 5,621,300 shares of its common stock, and warrants (the Warrants) to purchase 2,810,650 shares of its common stock. Each share of Series D preferred stock is convertible into five shares of the Company s common stock at a conversion price of $1.6275 per share.

The net proceeds to the Company, excluding the proceeds of any exercise of the warrants, was approximately $9.1 million which was allocated as described in Note 7(a). The Company intends to use these funds for research and product development activities, including costs of conducting preclinical studies and clinical trials, and for general corporate purposes.

The securities offered by the Company in the private placement were not registered under the Securities Act of 1933, as amended, and cannot be offered or sold in the United States absent registration or an applicable exemption from registration requirements. In December 2011, the Company filed a registration statement with the Securities and Exchange Commission registering the resale of the shares of common stock issuable upon conversion of the Series D preferred stock and the shares of common stock issuable upon exercise of the warrants issued in the private placement.

The Company is subject to specified cash penalties if it fails to maintain an effective registration statement with the Securities and Exchange Commission registering the resale of the shares of Common Stock issuable upon conversion of the Series D preferred stock and the shares of Common Stock issuable upon exercise of the Warrants. Such penalties are limited to a cumulative maximum penalty equal to 10% of the aggregate purchase price paid to the Company by Pillar for the Series D preferred stock. The Company is required to maintain the registration statement s effectiveness until no unregistered shares of Common Stock issued or issuable upon conversion of the Series D preferred stock or upon exercise of the Warrants remain outstanding or issuable, as applicable.

On August 5, 2010, the Company raised $15.1 million in gross proceeds from a registered direct offering of common stock to institutional investors. In the offering, the Company sold 4,071,005 shares of common stock and warrants to purchase 1,628,402 shares of common stock. The common stock and the warrants were sold in units at a price of $3.71 per unit, with each unit consisting of one share of common stock and warrants to purchase 0.40 shares of common stock. The warrants to purchase common stock have an exercise price of $3.71 per share, are exercisable immediately, and will expire if not exercised on or prior to August 5, 2015. The net proceeds to the Company from the offering, excluding the proceeds of any future exercise of the warrants, were approximately $14.1 million.

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Exhibit Index

Exhibit Number	Description	Filed Herewith	Incorporated by Reference to Filing		
			Form	Date	SEC File No.
3.1	Restated Certificate of Incorporation of Idera Pharmaceuticals, Inc., as amended.		10-Q	August 1, 2008	001-31918
3.2	Amended and Restated Bylaws of Idera Pharmaceuticals, Inc.		S-1	November 6, 1995	33-99024
3.3	Certificate of Ownership and Merger.		8-K	September 15, 2005	001-31918
4.1	Specimen Certificate for shares of Common Stock, $.001 par value, of Idera Pharmaceuticals, Inc.		S-1	December 8, 1995	33-99024
4.2	Certificate of Designations, Preferences and Rights of Series D Preferred Stock of the Company		8-K	November 10, 2011	001-31918
10.1	2008 Stock Incentive Plan, as amended		8-K	June 17, 2011	001-31918
10.2	2005 Stock Incentive Plan, as amended		10-Q	August 14, 2006	001-31918
10.3	Amended and Restated 1997 Stock Incentive Plan.		10-Q	May 15, 2001	000-27352
10.4	1995 Director Stock Option Plan.		8-K	June 10, 2008	001-31918
10.5	1995 Employee Stock Purchase Plan, as amended		8-K	June 17, 2011	001-31918
10.6	Non-Employee Director Nonstatutory Stock Option Agreement Granted under 1997 Stock Incentive Plan.		10-K	March 25, 2005	001-31918
10.7	Form of Incentive Stock Option Agreement Granted Under the 2005 Stock Incentive Plan.		8-K	June 21, 2005	001-31918
10.8	Form of Nonstatutory Stock Option Agreement Granted Under the 2005 Stock Incentive Plan.		8-K	June 21, 2005	001-31918
10.9	Form of Restricted Stock Agreement Under the 2005 Stock Incentive Plan.		10-Q	August 1, 2007	001-31918
10.10	Form of Incentive Stock Option Agreement Granted Under the 2008 Stock Incentive Plan.		8-K	June 10, 2008	001-31918
10.11	Form of Nonstatutory Stock Option Agreement Granted Under the 2008 Stock Incentive Plan.		8-K	June 10, 2008	001-31918
10.12	Form of Nonstatutory Stock Option Agreement (Non-Employee Directors) Granted Under the 2008 Stock Incentive Plan.		8-K	June 10, 2008	001-31918

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Exhibit Number	Description	Filed Herewith	Incorporated by Reference to Filing		
			Form	Date	SEC File No.
10.13	Form of Restricted Stock Agreement Under the 2008 Stock Incentive Plan.		8-K	June 10, 2008	001-31918
10.14	Policy on Treatment of Stock Options in the Event of Retirement, approved December 14, 2010.		10-K	March 10, 2011	001-31918
10.15	Employment Agreement dated October 19, 2005 between Idera Pharmaceuticals, Inc. and Dr. Sudhir Agrawal		10-Q	November 9, 2005	001-31918
10.16	Amendment dated December 17, 2008 to Employment Agreement by and between Idera Pharmaceuticals, Inc. and Dr. Sudhir Agrawal dated October 19, 2005.		8-K	December 18, 2008	001-31918
10.17	Amended and Restated Employment Letter Agreement by and between Idera Pharmaceuticals, Inc. and Louis J. Arcudi, III, Dated December 2, 2011.	X			
10.18	Director Compensation Program	X			
10.19	License Agreement dated February 21, 1990 and restated as of September 8, 1993 between Idera Pharmaceuticals, Inc. and University of Massachusetts Medical Center.		S-1	November 6, 1995	33-99024
10.20	Amendment No. 1 to License Agreement, dated as of February 21, 1990 and restated as of September 8, 1993, by and between University of Massachusetts Medical Center and Idera Pharmaceuticals, Inc., dated as of November 26, 1996.		10-Q	August 14, 1997	000-27352
10.21	Collaboration and License Agreement by and between Isis Pharmaceuticals, Inc., and Idera Pharmaceuticals, Inc., dated May 24, 2001.		10-Q	August 20, 2001	000-27352
10.22	Amendment No. 1 to the Collaboration and License Agreement, dated as of May 24, 2001 by and between Isis Pharmaceuticals, Inc. and Idera Pharmaceuticals, Inc., dated as of August 14, 2002.		10-K	March 31, 2003	000-27352
10.23	Master Agreement relating to the Cross License of Certain Intellectual Property and Collaboration by and between Isis Pharmaceuticals, Inc. and Idera Pharmaceuticals, Inc., dated May 24, 2001.		10-Q	August 20, 2001	000-27352
10.24	Exclusive License and Research Collaboration Agreement by and between Merck, Inc. and Idera Pharmaceuticals, Inc., dated December 8, 2006.		8-K	March 6, 2007	001-31918

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Exhibit Number	Description	Filed Herewith	Incorporated by Reference to Filing Form	Date	SEC File No.
10.25	License Agreement by and between Merck KGaA and Idera Pharmaceuticals, Inc., dated December 18, 2007.		10-K	March 11, 2008	001-31918
10.26	Amendment dated February 12, 2009 to the License Agreement by and between Merck KGaA and Idera Pharmaceuticals, Inc., dated December 18, 2007.		10-K	March 11, 2009	001-31918
10.27	Letter Agreement dated June 2, 2010 to the License Agreement by and between Merck KGaA and Idera Pharmaceuticals, Inc., dated December 18, 2007.		10-Q	August 5, 2011	001-31918
10.28	Letter Agreement dated May 27, 2011 to the License Agreement by and between Merck KGaA and Idera Pharmaceuticals, Inc., dated December 18, 2007.		10-Q	August 5, 2011	001-31918
10.29*	Termination Agreement dated November 30, 2011 by and between Idera Pharmaceuticals, Inc. and Merck KGaA concerning the License Agreement between Idera Pharmaceuticals, Inc. and Merck KGaA dated December 18, 2007 as amended.	X			
10.30	Unit Purchase Agreement by and among Idera Pharmaceuticals, Inc. and certain persons and entities listed therein, dated April 1, 1998.		10-K	April 1, 2002	000-27352
10.31	Registration Rights Agreement dated as of May 20, 2005 by and among Idera Pharmaceuticals, Inc., Purchasers and Pillar Investment Limited.		10-Q	August 9, 2005	001-31918
10.32	Registration Rights Agreement, dated March 24, 2006, by and among Idera Pharmaceuticals, Inc. and the Investors named therein.		8-K	March 29, 2006	001-31918
10.33	Registration Rights Agreement, dated March 24, 2006, by and among Idera Pharmaceuticals, Inc., Biotech Shares Ltd. and Youssef El Zein.		8-K	March 29, 2006	001-31918
10.34	Amendment No. 1 to the Registration Rights Agreement dated March 24, 2006, by and among Idera Pharmaceuticals, Inc. and Biotech Shares Ltd.		10-Q	August 14, 2006	001-31918
10.35	Form of Warrant issued to Investors in Idera Pharmaceuticals, Inc. s August 5, 2010 Financing.		10-Q	November 4, 2010	001-31918

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Exhibit Number	Description	Filed Herewith	Incorporated by Reference to Filing		
			Form	Date	SEC File No.
10.36	Consulting Agreement dated as of April 1, 2010 between Idera Pharmaceuticals, Inc. and Malcolm MacCoss, Ph.D.		10-Q	May 4, 2010	001-31918
10.37	Amendment dated as of December 31, 2010 amending Consulting Agreement dated as of April 1, 2010 between Idera Pharmaceuticals, Inc. and Malcolm MacCoss, Ph.D	X			
10.38	Consulting Agreement dated as of January 1, 2011 between Idera Pharmaceuticals, Inc. and Karr Pharma Consulting, LLC.	X			
10.39	Amendment dated December 19, 2011 amending Consulting Agreement dated as of January 1, 2011 between Idera Pharmaceuticals, Inc. and Karr Pharma Consulting, LLC.	X			
10.40	Convertible Preferred Stock and Warrant Purchase Agreement, dated November 4, 2011, among the Company and the Purchaser named therein.		8-K	November 10, 2011	001-31918
10.41	Registration Rights Agreement, November 4, 2011, among the Company and the Purchaser named therein.		8-K	November 10, 2011	001-31918
10.42	Form of Warrant issued to Purchaser pursuant to Convertible Preferred Stock and Warrant Purchase Agreement, dated November 4, 2011, among the Company and the Purchaser named therein.		8-K	November 10, 2011	001-31918
23.1	Consent of Independent Registered Public Accounting Firm.	X			
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002.	X			
31.2	Certification of Chief Financial Officer X pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002.	X			
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			

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Exhibit Number	Description	Filed Herewith	Incorporated by Reference to Filing		
			Form	Date	SEC File No.
101.INS**	XBRL Instance Document	X			
101.SCH**	XBRL Taxonomy Extension Schema	X			
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document	X			
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document	X			
101.LAB**	XBRL Taxonomy Extension Labels Linkbase Document	X			
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document	X			

Confidential treatment granted as to certain portions, which portions are omitted and filed separately with the Commission.
Management contract or compensatory plan or arrangement required to be filed as an Exhibit to the Annual Report on Form 10-K.

* Confidential treatment requested as to certain portions, which portions are omitted and filed separately with the Commission.

** Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.