

IDERA PHARMACEUTICALS, INC.

Form 10-K

March 10, 2010

Table of Contents

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-K

(Mark One)

- ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the Fiscal Year Ended December 31, 2009  
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  
(State or other jurisdiction  
of incorporation or organization)

04-3072298  
(I.R.S. Employer  
Identification No.)

167 Sidney Street  
Cambridge, Massachusetts  
(Address of principal executive offices)

02139  
(Zip Code)

(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 (Including Associated Preferred Stock Purchase Rights)	NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act: None

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

Edgar Filing: IDERA PHARMACEUTICALS, INC. - Form 10-K

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

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  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  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.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company   
(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

The approximate aggregate market value of the voting stock held by non-affiliates of the registrant was \$133,031,000 based on the last sale price of the registrant's common stock as reported on the NASDAQ Global Market on June 30, 2009. As of February 26, 2010, the registrant had 23,488,925 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 in June 2010 are incorporated by reference into Items 10, 11, 12, 13 and 14 of Part III of this Form 10-K.

---

**IDERA PHARMACEUTICALS, INC.**

**FORM 10-K**

**INDEX**

**Page**

**PART I.**

<u>Item 1.</u>	<u>Business</u>	1
<u>Item 1A.</u>	<u>Risk Factors</u>	19
<u>Item 1B.</u>	<u>Unresolved Staff Comments</u>	34
<u>Item 2.</u>	<u>Properties</u>	34
<u>Item 3.</u>	<u>Legal Proceedings</u>	34
<u>Item 4.</u>	<u>Reserved</u>	34

**PART II.**

<u>Item 5.</u>	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	35
<u>Item 6.</u>	<u>Selected Financial Data</u>	37
<u>Item 7.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	37
<u>Item 7A.</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	51
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u>	52
<u>Item 9.</u>	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	53
<u>Item 9A.</u>	<u>Controls and Procedures</u>	53
<u>Item 9B.</u>	<u>Other Information</u>	55

**PART III.**

<u>Item 10.</u>	<u>Directors, Executive Officers, and Corporate Governance</u>	55
<u>Item 11.</u>	<u>Executive Compensation</u>	55
<u>Item 12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	55
<u>Item 13.</u>	<u>Certain Relationships and Related Transactions, and Director Independence</u>	55
<u>Item 14.</u>	<u>Principal Accountant Fees and Services</u>	55

**PART IV.**

<u>Item 15.</u>	<u>Exhibits and Financial Statement Schedules</u>	56
<u>EX-10.15</u>		
<u>EX-23.1</u>		
<u>EX-31.1</u>		
<u>EX-31.2</u>		
<u>EX-32.1</u>		
<u>EX-32.2</u>		

IMO® and Idera® are our trademarks. All other trademarks and service marks appearing in this Annual Report on Form 10-K are the property of their respective owners.



**Table of Contents**

**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 wo expressions are intended to identify 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 SEC 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.

**Table of Contents**

**PART I.**

**Item 1. *Business***

**Overview**

We are engaged in the discovery and development of DNA- and RNA-based drug candidates targeted to Toll-Like Receptors, or TLRs, to treat infectious diseases, autoimmune and inflammatory diseases, cancer, and asthma and allergies, and for use as vaccine adjuvants. Drug candidates are compounds that we are developing and that have not been approved for any commercial use. TLRs are specific receptors present in immune system cells that recognize the DNA or RNA of bacteria or viruses and initiate an immune response. Relying on our expertise in DNA and RNA chemistry, we have designed and created proprietary TLR agonists and antagonists to modulate immune responses. 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.

Our business strategy is to advance applications of our TLR-targeted drug candidates in multiple disease areas simultaneously. We are advancing some of these applications through internal programs, and we seek to advance other applications through collaborative alliances with pharmaceutical companies. Collaborators provide the necessary resources and drug development experience to advance our compounds in their programs. 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 infectious diseases, autoimmune and inflammatory diseases, cancer, and asthma and allergies.

*Infectious disease program.* We are conducting two Phase 1 clinical trials of IMO-2125, a TLR9 agonist, in patients with chronic hepatitis C virus, or HCV, infection. In our first Phase 1 trial, we are evaluating IMO-2125 in patients with chronic HCV infection who had no response to a prior regimen of the current standard of care therapy. We refer to these patients as null responder HCV patients. We are conducting our second Phase 1 clinical trial of IMO-2125 in combination with ribavirin in patients with chronic HCV infection who have not received prior treatment for their HCV infection. We refer to these patients as treatment-naïve HCV patients.

*Autoimmune and inflammatory disease program.* We are conducting a Phase 1 clinical trial of IMO-3100, an antagonist of TLR7 and TLR9, in healthy subjects. We are also evaluating IMO-3100 and other antagonists of TLR7 and TLR9 in mouse models of lupus, rheumatoid arthritis, multiple sclerosis, psoriasis, colitis, pulmonary inflammation, and hyperlipidemia.

*Cancer program.* We are studying RNA-based compounds that act as agonists of TLR7 and/or TLR8, which we refer to as **stabilized immune modulatory RNA**, or SIMRA, compounds, in preclinical models of hematological cancers. In preclinical models, we have observed antitumor activity of a dual agonist of TLR7 and TLR8 as monotherapy and in combination with selected targeted drugs currently approved for cancer treatment.

*Respiratory disease program.* We currently are evaluating the next steps in developing IMO-2134, a TLR9 agonist, for respiratory diseases. IMO-2134 was created by us and selected by Novartis International Pharmaceutical, Ltd., or Novartis, as a lead drug candidate for asthma and allergies under our research collaboration with Novartis that was terminated by Novartis in February 2010. During the term of the research collaboration, Novartis initiated a Phase 1 clinical trial of IMO-2134.

In addition to our internal programs, we currently are collaborating with two pharmaceutical companies to advance other applications of our TLR-targeted compounds. We are collaborating with Merck KGaA for cancer treatment, excluding cancer vaccines, and with Merck & Co., Inc., or Merck & Co., for vaccine adjuvants in the fields of cancer, infectious diseases, and Alzheimer's disease. Merck KGaA is conducting clinical trials of IMO-2055, a TLR9 agonist, in head and neck cancer, colorectal cancer and non-small cell lung cancer. Merck KGaA and Merck & Co. are not related.



## **Table of Contents**

### **Our Business Strategy**

We believe that our drug candidates targeted to TLRs have broad potential applications in the treatment of infectious diseases, autoimmune and inflammatory diseases, cancer, and asthma and allergies, and as vaccine adjuvants. To develop the potential of our discoveries in multiple areas simultaneously, we are advancing some of these applications through internal programs and seeking to advance other applications through collaborations with pharmaceutical companies.

We have entered into collaborative alliances for application of our technology in multiple therapeutic areas. We believe that Merck KGaA and Merck & Co. provide the necessary resources and expertise to advance our programs with them. In addition, we have received upfront payments and milestone payments from Merck KGaA and Merck & Co. that have helped to finance our internal research and development programs. We may also receive additional payments if agreed upon milestones are achieved and royalties if any commercial products result from our collaborations. Our prior collaboration with Novartis provided the resources that led to the identification of a lead compound and initiation of a Phase 1 clinical trial.

As we continue to advance our clinical evaluation of IMO-2125 in chronic HCV infection, our clinical evaluation of IMO-3100 in autoimmune and inflammatory diseases, and our preclinical programs, we may enter into additional collaborations for one or more of these programs. In considering any future collaborations, we will assess the resources and expertise a potential collaborator may bring to the development and commercialization of our drug candidates.

We intend to stay at the forefront of TLR-based research and discovery by applying our chemistry-based approach to design and create novel and proprietary DNA- and RNA-based compounds targeted to TLRs. We use these compounds, which are synthetic chemical compounds, to populate our expanding research and development programs and to support our collaborations.

### **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, this time in a matter of days.

**Table of Contents**

**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. 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. Our compounds are designed to mimic the bacterial DNA and viral RNA that are recognized by TLR7, 8 or 9, with some of our compounds acting as agonists and others acting as antagonists.

*TLR9 Agonists*

Drug candidates that are agonists of TLR9 mimic bacterial DNA and induce immune responses through TLR9 that may be applicable to 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.

*TLR7 and TLR8 Agonists*

We are designing and creating novel synthetic RNA-based compounds that are agonists of TLR7 and/or TLR8, which we refer to as our SIMRA compounds. Our SIMRA compounds are designed to mimic viral RNA. In preclinical studies in cell culture and animal models, these TLR7 and/or TLR8 agonists induced immune responses that we believe may be applicable to the treatment of cancer and infectious diseases and as vaccine adjuvants. We are studying our TLR7 and TLR8 agonists in preclinical models of hematological cancers. In preclinical models, we have observed antitumor activity of these compounds as a monotherapy and in combination with selected targeted drugs currently approved for cancer treatment.

*TLR7 and TLR9 Antagonists*

We are creating novel classes of drug candidates that are designed to be antagonists of TLR7 and TLR9. Preclinical studies from independent researchers have suggested TLR7 and TLR9 may play a role in some autoimmune and inflammatory diseases. In cell-based experiments and animal models, our antagonists have blocked immune stimulation in the presence of specific agonists of TLR7 and specific agonists of TLR9. We have evaluated some of 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.

**Table of Contents****Research and Development Programs**

We and our collaborators 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.

***INTERNAL RESEARCH AND DEVELOPMENT PROGRAMS***

<b>Drug candidate(s)</b>	<b>Disease Area</b>	<b>Development Status</b>
<i>Infectious Diseases</i>		
IMO-2125 (TLR9 agonist)	Chronic Hepatitis C Virus Infection Null responder patients Treatment naïve patients	Phase 1 Clinical Trial Ongoing Phase 1 Clinical Trial Ongoing
TLR7, 8, and 9 agonists	Viral Infectious Diseases	Research
<i>Autoimmune and Inflammatory Diseases</i>		
IMO-3100 (dual TLR7/TLR9 antagonist)	Healthy Subjects	Phase 1 Clinical Trial Ongoing
	Lupus, Rheumatoid Arthritis, Multiple Sclerosis, Psoriasis, Colitis, Hyperlipidemia	Research
<i>Cancer</i>		
TLR7, TLR8 agonists	Hematological Cancers	Research
<i>Respiratory Diseases</i>		
IMO-2134 (TLR9 agonist)	Asthma, Allergies	Phase 1 Clinical Trial Initiated by Novartis during the Collaboration Period

***COLLABORATIVE ALLIANCES***

<b>Drug candidate(s)</b>	<b>Disease Area</b>	<b>Development Status</b>
<i>Merck KGaA Cancer</i>		
IMO-2055 (EMD 1201081) (TLR9 Agonist)		
IMO-2055	Squamous Cell Cancer of Head and Neck	Phase 2 Clinical Trial Ongoing
IMO-2055 in combination with Tarceva® and Avastin®	Non-small Cell Lung Cancer	Phase 1b Clinical Trial Ongoing
IMO-2055 in combination with Erbix® and chemotherapy	Colorectal Cancer	Phase 1b Clinical Trial Ongoing
<i>Merck &amp; Co. Vaccine Adjuvants</i>		
TLR7, 8, and 9 agonists	Cancer, Infectious Diseases, Alzheimer's Disease	Research

*Infectious Diseases*

We and others have conducted preclinical studies in human cell-based assays in which TLR agonists have activated cells of the immune system and induced these cells to secrete cytokines and other proteins that lead to further immune responses. We believe that certain agonists of TLRs 7, 8, and 9 can induce immune system responses, which may have potential therapeutic applicability in infectious diseases, including those caused by viruses.

Our most advanced TLR-targeted drug candidates in infectious diseases are our DNA-based TLR9 agonists, which have been shown to induce high levels of interferon-alpha in preclinical models. Interferon-alpha is a protein

## Table of Contents

that has been recognized to stimulate the immune system and is a component of the current standard of care for chronic HCV infection.

*Hepatitis C IMO-2125.* Chronic HCV infection causes inflammation of the liver, which significantly increases the risk that a patient will develop liver failure or liver cancer. The World Health Organization has reported that HCV is responsible for more than 50% of all liver cancer cases and two-thirds of all liver transplants in the developed world. The World Health Organization has estimated that about 200 million people are chronically infected with HCV worldwide and that an additional 3 million to 4 million people are infected each year. The Centers for Disease Control and Prevention have estimated that approximately 3 million people in the United States are chronically infected with HCV. Genotype 1 HCV, which is the type of HCV most resistant to current standard of care therapy, is the most prevalent form of HCV in the United States, Europe, and Japan. Currently, the standard of care treatment for chronic HCV infection is based on combination therapies that include a single recombinant interferon-alpha protein plus ribavirin, an antiviral medication.

We and other independent researchers have shown in preclinical studies that TLR9 agonists induce many proteins, including natural interferon-alpha proteins and other proteins with antiviral activity. We believe that the combined effect of these natural interferon-alpha proteins and other antiviral proteins may produce a broader or stronger antiviral effect than is obtained with a single recombinant interferon-alpha protein.

We have selected IMO-2125, a synthetic DNA-based TLR9 agonist, as our lead candidate for the treatment of chronic HCV infection. In preclinical models, including cultures of human immune cells and in nonhuman primates, IMO-2125 induced high levels of natural interferon and other antiviral proteins. The proteins induced by IMO-2125 in human immune cell cultures and in plasma from non-human primates dosed with IMO-2125 showed potent activity for inhibiting HCV RNA production in cell-based assays.

In May 2007, we submitted an Investigational New Drug, or IND, application for IMO-2125 to the United States Food and Drug Administration, or FDA. In September 2007, we initiated a Phase 1 clinical trial of IMO-2125 in patients with genotype 1 chronic HCV infection who had no response to a prior regimen of the current standard of care therapy. We refer to these patients as null responder HCV patients. The clinical trial is currently being conducted at six sites in the United States. In the trial, we are enrolling cohorts of ten patients at escalating IMO-2125 dose levels. To date, we have enrolled patients in four cohorts, evaluating IMO-2125 at 0.04 mg/kg/week, 0.08 mg/kg/week, 0.16 mg/kg/week and 0.32 mg/kg/week. Based on interim results from these cohorts, we extended the trial to a fifth dose level and are currently enrolling patients in a fifth cohort at 0.48 mg/kg/week. Of the ten patients in a cohort, eight are randomized to receive IMO-2125 treatment and two are randomized to receive placebo treatment. Patients receive a single dose of IMO-2125 or placebo once per week by subcutaneous injection for four weeks. The primary objective of the trial is to assess the safety of IMO-2125 at each dose level. We are also evaluating the effects of IMO-2125 on HCV RNA levels and on immune system activation in this trial.

In December 2009, we announced interim results from null responder HCV patients treated through the originally planned four cohorts of this trial. IMO-2125 was well tolerated by all patients in the four cohorts. IMO-2125-treated patients showed dose-dependent increases in natural interferon-alpha and other antiviral proteins including interferon-inducible protein 10 and 2,5-bisphosphate-oligoadenylate synthetase. In addition, an increasing percentage of patients, ranging from 40% at the 0.08 mg/kg/week dose level to 75% at the 0.32 mg/kg/week dose level, achieved a maximum reduction in viral load of 1 log<sub>10</sub> or more at least once during the four-week treatment period. In contrast, none of the patients who received placebo treatment or IMO-2125 at the 0.04-mg/kg/week dose level achieved a maximum reduction in viral load of 1 log<sub>10</sub> or greater at any time during the four-week treatment period. We plan to present detailed interim results of the trial at a scientific meeting in the second quarter of 2010.

In addition to the on-going Phase 1 clinical trial of IMO-2125 in null responder HCV patients, we are conducting a Phase 1 clinical trial of IMO-2125 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. We initiated the trial in October 2009. In this clinical trial, patients will receive IMO-2125 or a control article by subcutaneous injection once per week for four weeks at escalating dose levels in combination with daily oral administration of standard doses of ribavirin. A total of 15 patients are planned for the first cohort, with 12 randomized to receive IMO-2125 and ribavirin and three randomized to receive placebo and ribavirin as the control. Starting with the second cohort, 12 patients will be randomized to receive IMO-2125 and

## **Table of Contents**

ribavirin and six patients will be randomized to receive pegylated recombinant alfa-2a interferon and ribavirin as the control. The primary objective of the trial is to assess the safety and tolerability of IMO-2125 in combination with ribavirin. In addition, we plan to monitor the effect of treatment on HCV RNA levels. The clinical trial is currently being conducted at sites in France and Russia.

We have formed a Hepatitis C Clinical Advisory Board to advise us on the clinical development of IMO-2125 for the treatment of chronic HCV infection. Members of our Hepatitis C Clinical Advisory Board include leading hepatologists from Europe and the United States.

Following the completion of our Phase 1 study in null responder HCV patients, we plan to initiate in the second half of 2010 a clinical trial in which null responder HCV patients will receive IMO-2125 in combination with ribavirin for 12 weeks. With the data from this trial, together with the data from the two Phase 1 clinical trials, we plan to determine the next steps in the clinical development of IMO-2125 for HCV infection.

*Viral Diseases.* In addition to our TLR9 agonists such as IMO-2125, we have developed synthetic RNA-based compounds that mimic viral RNA and induce immune responses by functioning as agonists of TLR7 and/or TLR8. We are actively researching these compounds, and in human cell-based assays and *in vivo* in non-human primates, these compounds have induced immune responses that may be applicable to the treatment of viral infectious diseases.

### *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. 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 identified DNA-based compounds that in preclinical studies have acted as antagonists of TLR7 and TLR9. We believe that these antagonists may have application in the treatment of autoimmune diseases by inhibiting TLR7- or TLR9-mediated responses to the immune complex and thereby interfering with the inflammatory disease progression caused by activation of the immune system. Additionally, we believe that TLR antagonists may have application in the treatment of hyperlipidemia and other cardiovascular risk factors associated with some autoimmune diseases.

We have conducted evaluations of these compounds in various preclinical studies, including in strains of mice that are genetically predisposed to develop autoimmune disease similar to the human autoimmune disease lupus, in a mouse model of rheumatoid arthritis, in a mouse model of multiple sclerosis, in mouse models of psoriasis, in a mouse model of colitis, and in a mouse model of pulmonary inflammation. Data from each of these evaluations showed improvement in a number of disease parameters.

In August 2008, we selected IMO-3100 as a lead antagonist drug candidate and initiated preclinical development studies.

In October 2009, at the Annual Scientific Meeting of the American College of Rheumatology and Association of Rheumatology Health Professionals, we presented preclinical data from studies of IMO-3100 in combination with Enbrel<sup>®</sup>, an inhibitor of tumor necrosis factor alpha currently used for the treatment of rheumatoid arthritis. In a mouse model of collagen-induced arthritis, mice treated with a combination of IMO-3100 and Enbrel had lower arthritic scores, less inflammation, and less abnormal bone pathology as compared to mice treated with either agent



alone. The data also showed that the activity of a low Enbrel dosage was markedly enhanced when combined with IMO-3100 in this mouse model.

In February 2010 we presented data from a preclinical study that evaluated the pharmacodynamic mechanism of action of IMO-3100 in non-human primates. In this study, we assessed the response of peripheral blood mononuclear cells, or PBMCs, to TLR7 and TLR9 agonists at various times after subcutaneous administration of

## **Table of Contents**

IMO-3100 to non-human primates. Subcutaneous treatment with IMO-3100 was shown to inhibit induction of various cytokines and chemokines by TLR7 and TLR9 agonists in PBMC cultures, compared with PBMCs from blood samples taken prior to the dosing of IMO-3100. This inhibition was dependent on both the dosage of IMO-3100 administered and the time after administration of IMO-3100. IMO-3100 inhibition was specific to TLR7 and TLR9.

In November 2009, we submitted to the FDA an IND application for the clinical evaluation of IMO-3100 in autoimmune diseases. In January 2010, we initiated a Phase 1 clinical trial of IMO-3100 in healthy subjects. In this rising single-dose Phase 1 trial, IMO-3100 is being administered by subcutaneous injection. The primary objective is to evaluate safety and tolerability of IMO-3100. Secondary objectives are to characterize the pharmacokinetic profile of IMO-3100 and to assess the pharmacodynamic mechanism of action through measurement of the response of PBMCs to TLR7 and TLR9 agonists. The trial is being conducted at a single U.S. site.

We plan to use the results from this rising single-dose clinical trial to select dosages for an anticipated follow-up trial in healthy subjects. The purpose of the second Phase 1 trial would be to evaluate the safety, pharmacokinetics and pharmacodynamic mechanism of action of IMO-3100 with escalating doses in a study involving the subcutaneous administration of IMO-3100 once per week for four weeks. We intend to identify an initial autoimmune disease indication for further clinical development of IMO-3100 by the end of 2010.

We have formed an Autoimmune Disease Scientific Advisory Board with leading researchers in the field of autoimmune diseases to assist us with determining a clinical development strategy for our antagonist candidates.

### *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.

We have licensed our rights to the use of TLR9 agonists for the treatment of cancer under our collaboration with Merck KGaA, and are exploring on our own the use of TLR7 and TLR8 agonists for the treatment of cancer. We have created synthetic SIMRA compounds that mimic viral RNA and induce immune responses by functioning as agonists of TLR7 and TLR8. We are studying our SIMRA compounds in preclinical models of hematological cancers. In these preclinical models, we have observed antitumor activity of these compounds as a monotherapy and in combination with selected targeted drugs currently approved for cancer treatment.

### *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 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.

In May 2005, we entered into a research collaboration and option agreement and a separate license, development, and commercialization agreement with Novartis to discover, optimize, develop and commercialize TLR9 agonists as treatments for asthma and allergies. In September 2008, Novartis initiated a Phase 1 clinical trial of QAX935, a novel

agonist of TLR9. Novartis terminated the research collaboration and option agreement, effective as of February 2010. This termination cancels Novartis' option to implement the license, development and commercialization agreement. In connection with the termination, we regained all rights to QAX935, which we refer to as IMO-2134, without any financial obligations to Novartis, and are no longer subject to restrictions under the Novartis agreements on our right to develop TLR-targeted compounds, including TLR antagonist and TLR

## **Table of Contents**

antisense compounds, for respiratory diseases. Sponsorship of the trial initiated by Novartis has not been transferred to us. We are developing a strategy to advance the clinical development of IMO-2134 in asthma and allergy.

### *Collaborative Alliances*

#### *Cancer Merck KGaA*

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. Merck KGaA refers to IMO-2055 as EMD 1201081.

Prior to entering into our agreement with Merck KGaA, we had commenced clinical trials of IMO-2055, including a Phase 1b clinical trial of IMO-2055 in patients with non-small cell lung cancer. In January 2009, we initiated a Phase 1b clinical trial of IMO-2055 in patients with colorectal cancer. In April 2009, we initiated on behalf of Merck KGaA a Phase 1 clinical trial of IMO-2055 in healthy subjects. Merck KGaA agreed to reimburse us for costs associated with trials that we initiated and conducted, including costs associated with the Phase 1b clinical trials of IMO-2055 in patients with non-small cell lung cancer and in patients with colorectal cancer and the Phase 1 clinical trial of IMO-2055 in healthy subjects, that were incurred after February 4, 2008, which is the date our agreement with Merck KGaA became effective. In September 2009, Merck KGaA assumed sponsorship of our ongoing Phase 1b clinical trials of IMO-2055. Merck KGaA is now the sponsor of all clinical trials of IMO-2055 for the treatment of cancer and has assumed responsibility for all further clinical development of IMO-2055 in the treatment of cancer, excluding vaccines.

#### *Ongoing Clinical Trials of IMO-2055*

*Squamous Cell Carcinoma of the Head and Neck Phase 2 Clinical Trial.* In December 2009, Merck initiated a Phase 2 clinical trial of IMO-2055 in patients with recurrent or metastatic squamous cell carcinoma of the head and neck. Under the terms of our agreement with Merck KGaA, we received a milestone payment of 3.0 million (approximately \$4.1 million) from Merck KGaA in the first quarter of 2010 related to the initiation of this Phase 2 clinical trial of IMO-2055.

*Non-small Cell Lung Cancer Avastin and Tarceva Combination Phase 1b Clinical Trial.* In December 2007, we initiated a Phase 1b clinical trial of IMO-2055 in combination with Avastin and Tarceva, agents approved for the treatment of specific cancers, in patients with non-small cell lung cancer whose cancer had progressed during a prior course of standard therapy. We designed the trial to assess the safety of IMO-2055 in combination with standard dosages and schedules of Tarceva and Avastin and to determine the recommended dosage of IMO-2055 for potential use in a subsequent Phase 2 trial. In the trial, IMO-2055 was administered at four escalating dose levels of 0.08, 0.16, 0.32, and 0.48 mg/kg/week with fixed standard dose regimens of Avastin and Tarceva. Patients received IMO-2055 subcutaneously once a week, with each patient continuing to receive therapy until disease progression as determined by Response Evaluation Criteria in Solid Tumors, or RECIST, or another protocol-specified stopping criterion was met. In September 2009, we reported preliminary data from the dose-escalation portion of the trial. The combination of IMO-2055 with Avastin and Tarceva was well tolerated at all dose levels, and eight of the 16 patients enrolled in the dose-escalation portion of the trial remained on treatment for at least 18 weeks. Of the 13 patients evaluable for tumor response in the dose-escalation portion of the trial, three had a partial response and eight experienced stable disease. Based on the dose escalation portion of the trial, Merck KGaA selected a dose level of IMO-2055 for expanded patient recruitment to evaluate further the safety and pharmacokinetics of the combination.

*Colorectal Cancer Erbitux and Chemotherapy Combination Phase 1b Clinical Trial.* In January 2009, we initiated a Phase 1b clinical trial of IMO-2055 in combination with Erbitux and chemotherapy in patients with colorectal cancer

whose cancer had progressed during a prior course of standard therapy. We designed the trial to assess the safety of the IMO-2055, Erbitux, and chemotherapy combination and to determine the recommended dosage of IMO-2055 for potential use in a subsequent Phase 2 clinical trial. This trial was designed with a target enrollment of up to 50 patients. Under the protocol for the trial, IMO-2055 is being administered at three escalating dose levels with fixed standard dose regimens of Erbitux and chemotherapy. Patients are receiving IMO-2055

## **Table of Contents**

subcutaneously once a week, with each patient continuing to receive therapy until disease progression, as determined by RECIST, or another protocol-specified stopping criterion is met.

### *Prior Clinical Trials of IMO-2055.*

In April 2009, we initiated on behalf of Merck KGaA a Phase 1 clinical trial of IMO-2055 monotherapy in healthy subjects. The Phase 1 healthy subjects trial was designed to characterize further the pharmacokinetic and pharmacodynamic profiles of IMO-2055 after single and multiple weekly subcutaneous and intravenous administrations. All scheduled patient visits were completed by June 2009.

Prior to entering our collaboration with Merck KGaA, we conducted three Phase 1 clinical trials and one Phase 2 clinical trial of IMO-2055. The Phase 1 clinical trials included a rising dose trial in healthy subjects, a rising dose trial in advanced cancer patients, and a combination trial of IMO-2055 with gemcitabine and carboplatin chemotherapy in advanced cancer patients. The Phase 2 clinical trial was a Phase 2 Stage A clinical trial of IMO-2055 monotherapy in patients with metastatic or recurrent clear cell renal cancer. The study contained four arms, comprised of a total of 89 treatment-naïve and second-line patients randomly assigned to receive IMO-2055 subcutaneously at either 0.16 mg/kg/week or 0.64 mg/kg/week. The primary objective of the study was tumor response based on RECIST. Secondary objectives included time to progression, survival and safety. Progression-free survival was also analyzed. The primary objective was not achieved in the study. However, the median progression-free survival was 4.5 months and 1.9 months for the 0.16- and 0.64-mg/kg/week treatment-naïve patients, and 3.4 months and 4.3 months for the 0.16- and 0.64-mg/kg/week second-line patients. The median overall survival was 23.5 months over all arms and 58% of patients had stable disease. Two patients (one second-line and one treatment-naïve, and each receiving 0.64 mg/kg/week) had confirmed partial responses, and seven patients received weekly IMO-2055 treatment for at least one year. IMO-2055 treatment was generally well-tolerated with good dose intensity in all arms of the study.

### *Vaccine Adjuvants Merck & Co.*

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 TLR 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. As a result, we believe that TLR agonists have the potential to be used as adjuvants in vaccines.

In December 2006, we entered into a research collaboration with Merck & Co. and granted Merck & Co. 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 & Co. for cancer, infectious diseases, and Alzheimer's disease. The original term of the research collaboration was two years and Merck & Co. had the right to extend the research collaboration for two additional one-year periods. In November 2008, Merck & Co. extended the research collaboration for an additional year to December 2009, and in November 2009, Merck & Co. extended the research collaboration for the fourth and final year to December 2010. Merck & Co. is conducting preclinical studies to evaluate use of our TLR7, 8, and 9 agonists as vaccine adjuvants. In May 2008, we achieved a preclinical milestone under our collaboration with Merck & Co. involving one of our novel TLR9 agonists used as an adjuvant in cancer vaccines.

## **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 are currently a party to collaborations with Merck KGaA and Merck & Co.

**Table of Contents**

*Merck KGaA*

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 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, 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.

We have agreed that neither we nor our affiliates will, either directly or through a third party:

Develop or commercialize any TLR9 agonist for use in treating, curing, and delaying the onset or progression of cancer in humans; and

Develop or commercialize IMO-2055 for use outside treating, curing, and delaying the onset or progression of cancer in humans, except as part of vaccine products in the fields of oncology, infectious diseases and Alzheimer's disease, which we are pursuing under our collaboration with Merck & Co.

These restrictions will not limit our ability to research, develop and commercialize vaccine products containing IMO-2055 in the fields of oncology, infectious diseases, and Alzheimer's disease, and to research, develop and commercialize IMO-2125 outside the licensed field as a combination therapy or as a vaccine product.

Under the agreement, Merck KGaA 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 KGaA and the 10th anniversary of the product's first commercial sale in such country. If the patent rights expire in a particular country before the 10th anniversary of the product's first commercial sale in such country, Merck KGaA's obligation to pay us royalties will continue at a reduced royalty rate until such anniversary. In addition, the applicable product royalties may be reduced if Merck KGaA is required to pay royalties to third parties for licenses to intellectual property rights. Merck KGaA's royalty and milestone obligations may also be reduced if Merck KGaA terminates the agreement based on specified uncured material breaches by us. The agreement may be terminated by either party based upon material uncured breaches by the other party or by Merck KGaA at any time after providing Idera with advance notice of termination.

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 is now the sponsor of all clinical trials of IMO-2055 for the treatment of cancer and has assumed responsibility for all further clinical development of IMO-2055 in the treatment of cancer, excluding vaccines.

**Table of Contents**

*Merck & Co., Inc.*

In December 2006, we entered into an exclusive license and research collaboration agreement with Merck & Co. 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 & Co. worldwide exclusive rights to a number of our TLR7, 8, and 9 agonists for use in combination with Merck & Co.'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 & Co. can apply our agonists within these fields. We also agreed with Merck & Co. to engage in a two-year research collaboration to generate novel agonists targeting TLR7 and TLR8 and incorporating both Merck & Co. and Idera chemistry for use in vaccines in the defined fields. Under the agreement, Merck & Co. had the right to extend the collaboration for two additional one-year periods. In November 2008, Merck & Co. extended the research collaboration for an additional year to December 2009, and in November 2009, Merck & Co. extended the research collaboration for the fourth and final year to December 2010.

Under the terms of the agreement:

Merck & Co. paid us a \$20.0 million upfront license fee;

Merck & Co. purchased \$10.0 million of our common stock at \$5.50 per share;

Merck & Co. agreed to fund the research and development collaboration;

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

Merck & Co. 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 & Co. 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 & Co. 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 & Co.'s obligation to pay us royalties will continue at a reduced royalty rate until such anniversary, except that Merck & Co.'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 & Co. vaccine. In addition, the applicable royalties may be reduced if Merck & Co. is required to pay royalties to third parties for licenses to intellectual property rights, which royalties exceed a specified threshold. Merck & Co.'s royalty and milestone obligations may also be reduced if Merck & Co. terminates the agreement based on specified uncured

material breaches by us.

Merck & Co. may terminate the collaborative alliance without cause upon 180 days written notice to us during the research term and upon 90 days written notice to us after the research term has ended. 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.

## **Table of Contents**

Merck & Co. agreed, subject to certain exceptions, that for the duration of the research collaboration term, its ability to sell the shares of our common stock acquired by it under the agreement would be subject to specified volume limitations

### **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, which may assist us in identifying drug candidates. We have identified antisense compounds targeted to human TLRs 2, 3, 4, 5, 6, 7, 8, and 9 and to the TLR-associated signaling protein MyD88. We are studying these compounds for potential applications in autoimmune and inflammatory diseases.

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 our 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 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' 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 have entered into three 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.

## **Table of Contents**

Additionally, we have entered into six 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 specified percentage of any sublicense income. All of these 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 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, 2009, 2008 and 2007, we spent approximately \$18.6 million, \$16.2 million, and \$13.2 million on research and development activities. In 2009 and 2008, Merck KGaA sponsored approximately \$3.1 million and \$1.4 million of our research and development activities. In 2009, 2008 and 2007, Merck & Co. sponsored approximately \$0.8 million, \$1.5 million and \$1.1 million of our research and development activities.

## **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 TLR7, 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, 2010, we owned 66 U.S. patents and U.S. patent applications and 205 corresponding worldwide patents and patent applications 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, and IMO-3100.

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 2026.

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, 2010, our antisense patent portfolio included 101

## **Table of Contents**

U.S. patents and patent applications and 119 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 patents expire at various dates ranging from 2014 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 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**

The testing, manufacturing, labeling, advertising, promotion, distribution, import, export, and marketing, among other things, of drugs are extensively regulated by governmental authorities in the United States and other countries. In the U.S., the FDA regulates pharmaceutical products under the Federal Food, Drug, and Cosmetic Act, or FDCA, and other laws and regulations. Biological products are subject to regulation by the FDA under the FDCA, the Public Health Service Act, and related regulations. Both before and after approval for marketing is obtained, violations of regulatory requirements may result in various adverse consequences, including the FDA's delay in approving or refusal to approve pending applications or supplements, withdrawal of approval, suspension or withdrawal of an approved product from the market, operating restrictions, warning letters, product recalls, product seizures, injunctions, fines, and the imposition of civil or criminal penalties.

The steps required before a new pharmaceutical or biological product may be approved for marketing in the U.S. generally include:



nonclinical laboratory tests and animal tests under the FDA's good laboratory practices, or GLP, regulations;  
the submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin;

**Table of Contents**

adequate and well-controlled human clinical trials to establish the safety and efficacy of the investigational drug product for each indication or the safety, purity and potency of the biological product for its intended indication;

the submission to the FDA of a new drug application, or NDA, or a biologics license application, or BLA;

satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is made to assess compliance with the FDA's regulations on current good manufacturing practices, or cGMPs; and

FDA review and approval of the NDA or BLA.

Nonclinical tests include laboratory evaluation of product chemistry and formulation, as well as animal studies to assess the potential safety and pharmacological activity of a drug. The results of the nonclinical tests, together with manufacturing information and analytical and stability data, are submitted to the FDA as part of an IND, which must become effective before human clinical trials may be commenced. The IND will automatically become effective 30 days after its receipt by the FDA, unless the FDA before that time raises concerns or questions about the conduct of the trials as outlined in the IND. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed. If these issues are unresolved, the FDA may not allow the clinical trials to commence. There is no guarantee that submission of an IND will result in the FDA allowing clinical trials to begin.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Clinical trials are conducted under protocols, detailing the objectives of the trials, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND prior to beginning the trial. Each trial, including the study protocol and informed consent information for patients in the trial, must be reviewed and approved by an independent Institutional Review Board, or IRB, for each investigative site before it can begin at that site. Subjects must provide informed consent for all trials.

In Phase 1, the initial introduction of the drug into human subjects, the drug is usually tested to assess metabolism, pharmacokinetics and pharmacological actions and safety, including side effects associated with increasing doses and, if possible, early evidence of effectiveness. Phase 1 trials may also involve patients diagnosed with the disease or condition for which the study drug is intended and include assessments compatible with the proposed mechanism of action;

Phase 2 usually involves controlled trials in a limited patient population to:

evaluate preliminarily the efficacy of the drug for a specific, targeted condition,

determine dosage tolerance and appropriate dosage for further trials, and

identify possible adverse effects and safety risks.

Phase 3 trials generally further evaluate clinical efficacy and test further for safety within an expanded patient population with considerations of statistical design and power, to establish the overall risk-benefit relationship of the drug and to provide adequate information for the labeling of the drug.

Phase 1, 2, and 3 testing may not be completed successfully within any specified period, or at all. We, an IRB, or the FDA, may suspend or terminate clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Additional nonclinical toxicology studies are required after

clinical trials have begun. Some of these additional nonclinical toxicology studies may require several years to complete. The FDA can also request that additional clinical trials be conducted as a condition of product approval. Sponsors are required to publicly disseminate information about ongoing and completed clinical trials on a government website administered by the National Institutes of Health, or NIH, and are subject to civil monetary penalties and other civil and criminal sanctions for failing to meet these obligations. Our clinical testing program may be delayed or terminated due to factors such as:

unforeseen safety issues in the clinical trials and/or the continuing nonclinical toxicology studies;

inability to recruit or retain subjects or patients at the rate we expect;

**Table of Contents**

failure by the subjects and/or the investigators to adhere to protocol requirements;

inability to collect the information required to assess patients adequately for safety and efficacy; and

insufficient evidence of efficacy.

The results of the nonclinical and clinical studies, together with other detailed information, including information on the manufacture and composition of the product, are submitted to the FDA as part of an NDA or BLA for review and potential approval prior to the marketing and commercial shipment of the product. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. The FDA reviews a BLA to determine, among other things, whether the product is safe, pure and potent and the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, purity and potency. In most cases, the NDA or BLA must be accompanied by a substantial user fee. Before approving an NDA or BLA, the FDA will inspect the manufacturing facility or facilities used to produce the product for compliance with cGMP regulations. The FDA may deny an NDA or BLA if all applicable regulatory criteria are not satisfied or may require additional clinical, toxicology or manufacturing data. Even after an NDA or BLA results in approval to market a product, the FDA may limit the approved indications for which the product may be marketed or place other limitations that restrict the commercial application of the product.

If the FDA's evaluation of the NDA or BLA and the inspection of the manufacturing facilities are favorable, the FDA may issue an approval letter, which authorizes commercial marketing of the drug with specific prescribing information for specific indications. 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 FDA review and approval of a new NDA or BLA or of an NDA or BLA supplement before the change can be implemented. As a condition of NDA or BLA approval, the FDA may require additional clinical testing, including Phase 4 clinical trials, and may impose other conditions, including labeling restrictions and restrictions on distribution and use of the drug. The FDA may withdraw product approval if compliance with regulatory standards or conditions of the marketing approval is not maintained or if safety problems occur after the product reaches the market. In addition, the FDA requires surveillance programs to monitor the consistency of manufacturing and the safety of approved products that have been commercialized. Holders of an approved NDA or BLA are required to report certain adverse reactions and production problems to the FDA, to provide updated safety and efficacy information, and to comply with requirements concerning advertising and promotional labeling. The agency has the power to require changes in labeling or to prevent further marketing of a product based on new data that may arise after commercialization. In addition, quality control and manufacturing procedures must continue to conform to cGMP requirements after approval, to assure and preserve the long-term stability of the drug product. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP, including its extensive procedural, substantive and record keeping requirements. Also, new federal, state, or local government requirements may be established that could delay or prevent regulatory approval of our products under development.

If the FDA's evaluation of the NDA or BLA or manufacturing facilities is not favorable, the FDA may refuse to approve the NDA or BLA or issue a complete response letter. The complete response letter describes the deficiencies that the FDA has identified in an application and, when possible, recommends actions that the applicant might take to place the application in condition for approval. Such actions may include, among other things, conducting additional safety or efficacy studies after which the sponsor may resubmit the application for further review. Even with the completion of this additional testing or the submission of additional requested information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. With limited exceptions, the FDA may withhold approval of an NDA or BLA, regardless of prior advice it may have provided or commitments it may have

made to the sponsor.

It may take many years and the expenditure of substantial resources to evaluate fully the safety and efficacy of a drug candidate or the safety, purity and potency of a biological product candidate in nonclinical and clinical studies, to qualify appropriate drug or biological product formulations, and to ensure manufacturing processes are compliant with regulations. Data obtained in nonclinical studies or early clinical studies may not be indicative of results that might be obtained in later clinical trials that are often critical to the regulatory approval process.

## **Table of Contents**

Formulation and/or manufacturing changes may cause delays in the development plan or require re-testing. Many of the activities may be subject to varying interpretations that could limit, delay, or prevent regulatory approval. In addition, requirements for regulatory approval may change at any time during the course of clinical or nonclinical studies, requiring some facets of those studies to be repeated at additional cost and time.

We will also be subject to a variety of foreign regulations governing clinical trials and the marketing and sale of our products. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must be obtained prior to the commencement of marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. For marketing outside the U.S., we are also subject to foreign regulatory requirements governing human clinical trials. The requirements governing the conduct of clinical trials, product licensing, approval, pricing, and reimbursement vary greatly from country to country.

In addition to regulations enforced by the FDA, we are also subject to regulation under the Occupational Safety and Health Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, and other current and potential future federal, state, or local regulations. Our research and development activities involve the controlled use of hazardous materials, chemicals and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state, federal, and local regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources.

Our collaborators under the various license agreements we have completed have assumed responsibility for regulatory issues pertinent to any drug candidates or marketed products that may arise from our collaborations.

## **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 one contract manufacturer 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 agreements with Merck KGaA and Merck & Co., our collaborators are responsible for manufacturing the drug candidates.

## **Competition**

We are developing our TLR-targeted drug candidates for use in the treatment of infectious diseases, autoimmune and inflammatory diseases, asthma and allergies, and cancer, and 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.

Some of the 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.

If we are able to commercialize IMO-2125 for chronic HCV infection, we will face competition from the currently marketed therapies and may face competition from non-TLR targeted therapies in late stage development

## **Table of Contents**

such as protease inhibitors being developed by Vertex Pharmaceuticals, Inc. and Merck & Co. We are also aware of numerous other compounds in clinical trials that target chronic HCV infection through a number of different mechanisms of action, and we believe that there are many additional potential HCV treatments in research or early development. There are also a number of companies developing TLR compounds for chronic HCV infection, including Dynavax Technologies Corporation and Anadys Pharmaceutical, Inc.

Our principal competitors developing TLR-targeted compounds for our autoimmune and inflammatory diseases program include Pfizer, Inc. and Dynavax Technologies Corporation, with its collaborator, GlaxoSmithKline and for our respiratory disease program include Dynavax Technologies Corporation in collaboration with AstraZeneca Pharmaceuticals plc, Pfizer, Inc., in collaboration with Sanofi-Aventis Groupe, Cytos Biotechnology and VentiRx Pharmaceuticals.

For our partnered programs, our principal competitors developing TLR-targeted compounds for cancer treatment include Pfizer, Inc., Anadys Pharmaceutical, Inc. and VentiRx Pharmaceuticals. Merck & Co.'s vaccines using our TLR7, 8 or 9 agonists as adjuvants may compete with vaccines being developed or marketed by GlaxoSmithKline plc, Novartis, Dynavax Technologies Corporation, VaxInnate, Inc., Intercell AG, Cytos Biotechnology AG and Celldex Therapeutics, Inc.

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, 2010, we employed 40 individuals. Of our 40 employees, 24 are engaged in research and development and 22 hold a Ph.D., M.D., or equivalent degree. None of our employees are covered by a collective bargaining agreement, and we consider relations with our employees to be good.

## **Information Available on the Internet**

Our internet address is [www.iderapharma.com](http://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.

**Table of Contents**

**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, 2009, we had an accumulated deficit of \$333.7 million. We have incurred losses of \$73.5 million since January 1, 2001. We also incurred losses of \$260.2 million prior to December 31, 2000 during which time we were primarily involved in the development of 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 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 may 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, cash equivalents, and investments of \$40.2 million at December 31, 2009. We believe that our existing cash, cash equivalents, and investments will be sufficient to fund our operations at least through December 31, 2011 based on our current operating plan, which assumes that we will continue to conduct our three ongoing clinical trials and that we will conduct the 12-week Phase 1b clinical trial of IMO-2125 in null responder HCV patients and the 4-week Phase 1 clinical trial of IMO-3100 in healthy subjects that we plan to initiate in 2010 but does not assume that we will conduct any other clinical trials. We will need to raise additional funds to operate our business beyond such date. However, if we elect to conduct additional clinical trials beyond our ongoing clinical trials and the planned IMO-2125 and IMO-3100 trials, we may need to raise funds prior to such date.

We may 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 success of our clinical and preclinical development programs;

the success of our existing strategic collaborations with Merck KGaA and Merck & Co.;

the cost, timing and outcome of regulatory reviews;

**Table of Contents**

the receptivity of the capital markets to financings by biotechnology companies; 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 success of IMO-2125, IMO-3100 and our collaborative alliances. If we or our collaborators are unable to successfully develop and commercialize our drug candidates, or experience significant delays in doing so, our business will be materially harmed.***

We are investing a significant portion of our time and financial resources in the development of our clinical stage lead drug candidates for infectious diseases, IMO-2125, and for autoimmune and inflammatory diseases, IMO-3100. We anticipate that our ability to generate product revenues will depend heavily on the successful development and commercialization of IMO-2125, IMO-3100 and other drug candidates including drug candidates being developed by our collaborators. The commercial success of these drug candidates will depend on several factors, including the following:

acceptable safety profile during clinical trials;

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

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

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

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;

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 our drug candidates following approval.

**Table of Contents**

Our efforts to commercialize IMO-2125 and IMO-3100 are at early stages, as we are currently conducting Phase 1 safety clinical trials of these drug candidates. If we are not successful in commercializing these or our other drug candidates, or are significantly delayed in doing so, our business will be materially harmed.

***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.

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, 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<sup>®</sup>, for HCV infection. In July 2007, Anadys Pharmaceuticals, Inc. and its partner 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<sup>®</sup>, which comprises a TLR9 agonist covalently attached to a ragweed antigen.

There are few data on the long-term clinical safety of our lead compounds under conditions of prolonged use in humans, or on any long-term consequences subsequent to human use. Effects seen in preclinical studies, even if not observed in clinical trials, may result in limitations or restrictions on our clinical trials. We may experience numerous unforeseen events during, or as a result of, preclinical testing, nonclinical testing, or the clinical trial process that could delay or inhibit our ability to receive regulatory approval or to commercialize our products, including:

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;

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;

**Table of Contents**

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 Stage A of our Phase 2 clinical trial of IMO-2055 in renal cell cancer, enrollment was slower than projected due to the then-recent approval of two new therapies, Sutent® and Nexavar®, developed by other companies for treatment of the same patient populations. In addition, in our on-going Phase 1 clinical trial of IMO-2125 in patients with chronic HCV infection who have not responded to the current standard of care therapy, completion of each cohort has taken 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;

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;

**Table of Contents**

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. 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 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 based upon TLR technology being developed by our competitors have negative clinical trial results or otherwise are viewed negatively, the perception of our TLR technology and market acceptance of our products could be impacted negatively.

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 infectious diseases, autoimmune and inflammatory diseases, asthma and allergies, and cancer, and 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.

Some of the 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.

## **Table of Contents**

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 President, Chief Executive Officer and Chief Scientific 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 worldwide. 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, 2012, 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 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, non-clinical 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, we are conducting clinical trials of IMO-2125 and IMO-3100. 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.

## **Table of Contents**

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 violations of 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;

- 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;

- finest;

- 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

## **Table of Contents**

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**

#### ***We need to establish additional collaborative alliances in order to succeed.***

We seek to advance our products through collaborative alliances with pharmaceutical companies. Collaborators provide the necessary resources and drug development experience to advance our compounds in their programs. 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 infectious diseases, autoimmune and inflammatory diseases, cancer, and asthma and allergies. 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, our ability to advance our compounds will be jeopardized and we may fail to meet our business objectives. If we cannot enter into additional collaboration agreements, we may not be able to obtain the expertise and resources necessary to achieve our business objectives. We face, and will continue to face, significant competition in seeking appropriate collaborators. 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 or other alternative arrangements. The terms of any collaborations or other arrangements that we establish, if any, may not be favorable to us.

#### ***Our existing collaborations 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 & Co. 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. The success of our collaborative alliances, if any, will depend heavily on the efforts and activities of our collaborators. Our existing collaborations 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;

**Table of Contents**

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;

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. 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 underfund 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 them in May 2005. Such terminations or expirations may adversely affect us financially and could harm our business reputation in the event we elect to pursue collaborations that ultimately expire or are terminated in such a manner.

**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 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

## **Table of Contents**

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.

***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 some other patents or patent applications that are related to our products. Third parties may own or control these patents and patent applications in the United States and abroad. 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.

***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. However, we are party to seven 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 2014 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 USPTO 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

## **Table of Contents**

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 products 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 products, apply for regulatory approvals and ultimately commercialize products, we need to develop, contract for or otherwise arrange for the necessary manufacturing capabilities.

We currently rely upon third parties to produce material for nonclinical, preclinical 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 and rely on only one contract manufacturer. If this contract manufacturer ceases to manufacture active material for us, our business will be negatively impacted.

There are a limited number of manufacturers that operate under the FDA's cGMP regulations capable of manufacturing our products. 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 products on a timely basis, or to do so on commercially reasonable terms, we may not be able to complete development of our products or market them.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured products 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 products that is necessary for the manufacture of our products; 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. Any failure by our third-party manufacturers to comply with such requirements, regulations or standards could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. Such failure could also result in sanctions being imposed, including fines, injunctions, civil penalties,

## **Table of Contents**

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 TLR-targeted 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 is manufactured or a change of a third-party manufacturer, may require prior FDA review and approval in accordance with the FDA's cGMP 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 product. 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.

***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 products, 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 products 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 products. We depend on independent clinical investigators, contract research organizations and other third-party service providers in the conduct of the clinical trials of our products and expect to continue to do so. We have contracted with contract research organizations to manage our current Phase 1 clinical trials of IMO-2125 in patients with chronic HCV infection and our Phase 1 clinical trial of IMO-3100 in healthy subjects. 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 products. 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 and 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

## **Table of Contents**

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;

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 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.

Moreover, the U.S. Congress is currently considering legislation that would dramatically overhaul the health care system, including the possibility of creating a government health care plan. As part of this legislative initiative, Congress is considering a number of proposals that are intended to reduce or limit the growth of health care costs, which could significantly change the market for pharmaceutical products. If such proposals are enacted, they could, among other things, increase pressure on drug pricing or make it more costly for patients to gain access to prescription drugs at affordable prices. This could force individuals who are prescribed drugs to pay significant out-of-pocket costs or pay for the prescription entirely by themselves. As a result of such initiatives, market acceptance and commercial success of our product may be limited and our business may be harmed.

## **Table of Contents**

Third-party payors are challenging the prices charged for medical products and services, and many third-party payors limit reimbursement for newly-approved healthcare 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 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 may develop, which would result in lower product revenues 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, our stockholder rights plan 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, by-laws, and stockholder rights plan 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;

**Table of Contents**

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.

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, 2007 to March 1, 2010, the closing sales price of our common stock ranged from a high of \$15.41 per share to a low of \$4.60 per share. The stock market has also experienced significant price and volume fluctuations, particularly within the past two 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:

results of 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.

**Table of Contents**

**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 and we have specified rights to sublease this facility and a five-year renewal option.

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

None.

**Item 4. *Reserved.***



**Table of Contents****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.

	<b>High</b>	<b>Low</b>
<b>2008</b>		
First Quarter	\$ 13.60	\$ 7.65
Second Quarter	15.60	9.88
Third Quarter	15.40	10.90
Fourth Quarter	14.50	5.59
<b>2009</b>		
First Quarter	\$ 9.19	\$ 4.50
Second Quarter	7.46	5.02
Third Quarter	8.11	5.20
Fourth Quarter	8.50	4.48

As of March 1, 2010, we had approximately 150 common stockholders of record.

**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.

**Table of Contents****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, 2004 through December 31, 2009 with the cumulative total return of the NASDAQ Market Index, the NASDAQ Biotechnology Index, the Russell 2000 Index and an SIC Group Index comprised of publicly traded companies with SIC Code 2836 (biological products). This graph assumes an investment of \$100 on December 31, 2004 in the Company's common stock and in each of the indices and assumes that dividends are reinvested. In future filings, the Company intends to compare the cumulative stockholder return on its common stock to the NASDAQ Biotechnology Index and the Russell 2000 Index.

**COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN**

	<b>12/31/04</b>	<b>12/31/05</b>	<b>12/31/06</b>	<b>12/31/07</b>	<b>12/31/08</b>	<b>12/31/09</b>
<b>IDERA PHARMACEUTICALS, INC.</b>	<b>100.00</b>	<b>127.08</b>	<b>140.36</b>	<b>341.15</b>	<b>200.00</b>	<b>134.64</b>
<b>NASDAQ MARKET INDEX</b>	<b>100.00</b>	<b>101.41</b>	<b>114.05</b>	<b>123.94</b>	<b>73.43</b>	<b>105.89</b>
<b>NASDAQ BIOTECHNOLOGY INDEX</b>	<b>100.00</b>	<b>117.54</b>	<b>117.37</b>	<b>121.37</b>	<b>113.41</b>	<b>124.58</b>
<b>RUSSELL 2000 INDEX</b>	<b>100.00</b>	<b>104.55</b>	<b>123.76</b>	<b>121.82</b>	<b>80.66</b>	<b>102.58</b>
<b>SIC GROUP INDEX</b>	<b>100.00</b>	<b>113.36</b>	<b>104.63</b>	<b>102.64</b>	<b>103.69</b>	<b>99.14</b>

**Table of Contents****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.

	<b>Year Ended December 31,</b>				
	<b>2009</b>	<b>2008</b>	<b>2007</b>	<b>2006</b>	<b>2005</b>
	<b>(In thousands, except per share data)</b>				
<b>Statement of Operations Data:</b>					
Alliance revenue	\$ 34,518	\$ 26,450	\$ 8,124	\$ 2,425	\$ 2,477
Operating expenses:					
Research and development	18,570	16,152	13,195	12,705	11,170
General and administrative	8,561	9,798	9,656	6,280	5,130
Total operating expenses	27,131	25,950	22,851	18,985	16,300
Income (loss) from operations	7,387	500	(14,727)	(16,560)	(13,823)
Other income (expense):					
Investment income, net	145	1,344	1,668	505	369
Interest expense	(3)	(92)	(149)	(425)	(252)
Foreign currency exchange loss	(27)	(267)			
Income (loss) before income taxes	7,502	1,485	(13,208)	(16,480)	(13,706)
Income tax benefit (provision)	44	24		(45)	
Net income (loss)	\$ 7,546	\$ 1,509	\$ (13,208)	\$ (16,525)	\$ (13,706)
Basic net income (loss) per share	\$ 0.32	\$ 0.07	\$ (0.62)	\$ (0.99)	\$ (0.99)
Diluted net income (loss) per share	\$ 0.31	\$ 0.06	\$ (0.62)	\$ (0.99)	\$ (0.99)
Shares used in computing basic net income (loss) per common share(1)	23,420	22,655	21,221	16,625	13,886
Shares used in computing diluted net income (loss) per common share(1)	24,079	25,331	21,221	16,625	13,886
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and investments	\$ 40,207	\$ 55,606	\$ 23,743	\$ 38,187	\$ 8,376
Working capital	23,054	32,099	15,908	30,984	4,998
Total assets	47,639	59,400	27,714	40,541	9,989
Capital lease obligations	28	49	70	10	17
Note payable			1,143		
4% convertible subordinated notes payable				5,033	5,033

Accumulated deficit	(333,679)	(341,225)	(342,734)	(329,526)	(313,000)
Total stockholders' equity (deficit)	33,105	22,167	7,719	12,237	(335)

(1) Computed on the basis described in Note 13 of notes to financial statements appearing elsewhere in this Annual Report on Form 10-K.

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

**Overview**

We are engaged in the discovery and development of DNA- and RNA-based drug candidates targeted to Toll-Like Receptors, or TLRs, to treat infectious diseases, autoimmune and inflammatory diseases, cancer, and asthma and allergies, and for use as vaccine adjuvants. Drug candidates are compounds that we are developing and that have not been approved for any commercial use. TLRs are specific receptors present in immune system cells that recognize the DNA or RNA of bacteria or viruses and initiate an immune response. Relying on our expertise in DNA and RNA chemistry, we have designed and created proprietary TLR agonists and antagonists to modulate immune responses. 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.

Our business strategy is to advance applications of our TLR-targeted drug candidates in multiple disease areas simultaneously. We are advancing some of these applications through internal programs, and we seek to advance

## **Table of Contents**

other applications through collaborative alliances with pharmaceutical companies. Collaborators provide the necessary resources and drug development experience to advance our compounds in their programs. 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 infectious diseases, autoimmune and inflammatory diseases, cancer, and asthma and allergies. We are conducting two Phase 1 clinical trials of IMO-2125, a TLR9 agonist, in patients with chronic hepatitis C virus, or HCV, infection. We are conducting a Phase 1 clinical trial of IMO-3100, an antagonist of TLR7 and TLR9, in healthy subjects.

In addition to our internal programs, we currently are collaborating with two pharmaceutical companies to advance other applications of our TLR-targeted compounds. We are collaborating with Merck KGaA for cancer treatment, excluding cancer vaccines. Merck KGaA is conducting two Phase 1b clinical trials and one Phase 2 clinical trial in cancer indications. We also are collaborating with Merck & Co., Inc., or Merck & Co., for vaccine adjuvants in the fields of cancer, infectious diseases, and Alzheimer's disease. Merck KGaA and Merck & Co. are not related.

At December 31, 2009, we had an accumulated deficit of \$333.7 million. We may incur substantial operating losses in future periods. We do not expect to generate significant funds until we successfully complete development and obtain marketing approval for products, either alone or in collaborations with third parties, which we expect will take a number of years. In order to commercialize our products, we need to address a number of technological challenges and to comply with comprehensive regulatory requirements. In 2010, we expect that our research and development expenses will be higher than our research and development expenses in 2009 as we expand our clinical trials of IMO-2125 and IMO-3100 and accelerate our preclinical studies on TLR antagonists and on agonists of TLR7 and TLR8.

## **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. 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 and

stock-based compensation fit the description of critical accounting policies and estimates.

*Revenue Recognition*

Our corporate strategy includes entering into collaborative license and development agreements with pharmaceutical companies for the development and commercialization of our product candidates. The terms of our

**Table of Contents**

agreements have included non-refundable license fees, funding of research and development, payments based upon achievement of clinical and preclinical development milestones and royalties on product sales.

Our policy for recognizing revenue requires that four basic criteria are met before we can recognize revenue:

persuasive evidence of an arrangement exists;

delivery has occurred, services have been rendered or obligations have been satisfied;

the fee is fixed or determinable; and

collectability is reasonably assured.

Determination of the last three criteria are based on management's judgments regarding the fixed nature of the fee charged for services rendered or products delivered and the collectability of these fees. Should changes in conditions cause management to determine these criteria are not met for any future transactions, revenues recognized for any reporting period could be adversely affected.

When evaluating multiple element arrangements, we consider whether the components of the arrangement represent separate units of accounting.

We recognize revenue from non-refundable upfront fees received under collaboration agreements, not specifically tied to a separate earnings process, ratably over the term of our contractual obligation or our estimated continuing involvement under the research arrangement. If the estimated period of continuing involvement is subsequently modified, we will modify the period over which the upfront fee is recognized, accordingly, on a prospective basis.

We recognize revenue from reimbursements earned in connection with our research and development collaboration agreements as related research and development costs are incurred, and our contractual services are performed, provided collectability is reasonably assured. We include amounts contractually owed us under these research and development collaboration agreements, including any earned but unbilled receivables, in trade accounts receivable 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 specifically associated with a separate earnings process, we recognize revenue when the specific performance obligation is completed. Performance obligations typically consist 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. We recognize revenue from milestone payments received under collaboration agreements when earned, provided that the milestone event is substantive, its achievability was not reasonably assured at the inception of the agreement, we have no further performance obligations relating to the event and collectability is reasonable assured. In the event that the agreement provides for payment to be made subsequent to our standard payment terms, we recognize revenue when payment is 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, in connection with our existing collaboration agreements, we have recorded on our balance sheet short-term and long-term deferred revenue based on our best estimate of when such revenue will be recognized. However, this estimate is based on our collaboration agreements and our current operating plan and, if either should change, we may recognize a different amount of deferred revenue over the next twelve-month period.

Our estimate of deferred revenue also reflects management's 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



## **Table of Contents**

change in the future. 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 future 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 the date of grant. Our policy is to charge the fair value of stock options as an expense on a straight-line basis over the vesting period. We are also required to record compensation cost for the non-vested portion of stock-based awards granted prior to January 1, 2006, when we adopted ASC 718-10, over the requisite service periods for the individual awards based on the estimated fair value adjusted for forfeitures. 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. For options granted during 2007 and 2006, we use an expected option life (1) based on the average of the option term and the option vesting period for standard options and (2) based on actual experience of options held by employees holding options with similar characteristics for those options that do not meet the SEC's criteria for using the simplified method. For options granted after December 31, 2007, 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, net income and earnings 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, may not provide reliable measures of the fair values of our stock-based compensation.

### *New Accounting Pronouncements*

On January 1, 2009, we adopted Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 808-10 (*Prior authoritative literature: Emerging Issues Task Force (EITF) 07-1, Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*) on a retrospective basis for all collaborative arrangements existing as of January 1, 2009. ASC 808-10 defines collaborative arrangements and establishes reporting requirements for transactions between participants in collaborative arrangements and between participants in the arrangement and third parties. The adoption of ASC 808-10 did not have a material impact on our financial statements.

In June 2009, the FASB issued new guidance concerning the organization of authoritative guidance under Generally Accepted Accounting Principles, or GAAP. This new guidance created the FASB Accounting Standards Codification, or ASC. The ASC has become the single source of authoritative nongovernmental GAAP. Rules and interpretive releases of the SEC under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. The ASC is effective for interim and annual periods ending after September 15, 2009. On its effective date, the ASC superseded all then-existing non-SEC accounting and reporting standards. All other non-SEC

accounting literature not included in the ASC has become nonauthoritative. As the ASC is not intended to change or alter existing GAAP, it did not have any impact on our consolidated financial statements upon adoption.

During the second quarter of 2009, we adopted ASC 825-10 (*Prior authoritative literature: FASB Staff Position No. FAS 107-1 and APB 28-1, Interim Disclosures about Fair Value of Financial Instruments*). ASC

**Table of Contents**

825-10 requires disclosures about the fair value of financial instruments in interim as well as in annual financial statements. The adoption of ASC 825-10 did not have a significant impact on our financial position or results of operations.

During the second quarter of 2009, we adopted ASC 820-10 (*Prior authoritative literature: FASB Staff Position No. FAS 157-4, Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly*). ASC 820-10 provides additional guidelines for making fair value measurements, provides authoritative guidance in determining whether a market is active or inactive and whether a transaction is distressed. ASC 820-10 requires additional disclosures of the input and valuation techniques used to measure fair value and the defining of the major security types comprising debt and equity securities held based upon the nature and risk of the security. The adoption of ASC 820-10 did not impact our financial position or results of operations.

During the second quarter of 2009, we adopted ASC 320-10 (*Prior authoritative literature: FASB Staff Position No. FAS 115-2 and FAS 124-2, Recognition and Presentation of Other-Than-Temporary Impairments*). ASC 320-10 changes existing accounting requirements for other-than-temporary impairment of debt securities. The adoption of ASC 320-10 did not impact our financial position or results of operations.

During the second quarter of 2009, we adopted ASC 855-10 (*Prior authoritative literature: FASB Statement of Financial Accounting Standards No. 165, Subsequent Events*). ASC 855-10 is similar to the subsequent events guidance in the current auditing literature except that it clarifies and discloses the period during which companies monitor subsequent events in order to determine what impact, if any, the subsequent events have on the information disclosed in the financial statements and footnotes. The adoption of ASC 855-10 did not impact our financial position or results of operations.

In October 2009, the FASB issued new accounting requirements for accounting for revenue recognition under multiple-element arrangements, which will be effective for fiscal years beginning after June 15, 2010. We are currently evaluating the effect of these new requirements on our financial statements.

**Results of Operations*****Years ended December 31, 2009, 2008 and 2007******Alliance Revenue***

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

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

	Year Ended December 31,			Annual Percentage Change	
	2009	2008	2007	2009/2008	2008/2007
	(In millions)				
License fees	\$ 22.2	\$ 21.5	\$ 6.6	3%	226%
Research and development	3.9	2.9	1.1	34%	164%

Edgar Filing: IDERA PHARMACEUTICALS, INC. - Form 10-K

Milestones	8.3	2.0	0.3	315%	567%
Other	0.1	0.1	0.1		
Total alliance revenue	\$ 34.5	\$ 26.5	\$ 8.1	30%	227%

*License Fees.* License fees primarily include license fee revenue recognized under our collaborations with Merck KGaA, Merck & Co. and Novartis. License fee revenue during 2009, 2008 and 2007 was comprised of a portion of upfront license fee payments and, if applicable, any research period extension payments we recognized from collaborative alliances, with which we are still involved during the period. We recognize license fee revenue

**Table of Contents**

ratably over the expected period of our continuing involvement in the collaborations, which generally represents the estimated research period of the agreement.

The following table is a summary of license fees recognized under our three principal collaborations:

Collaborator	Year Ended December 31,		
	2009	2008	2007
	(In millions)		
Merck KGaA	\$ 17.1	\$ 15.5	
Merck & Co.	5.0	5.0	5.0
Novartis		0.8	1.3

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 are recognizing the \$40.0 million upfront payment as revenue over the twenty eight-month research term. We received a \$20.0 million upfront payment from Merck & Co. in December 2006. We are recognizing the \$20.0 million upfront payment as revenue over the two-year initial research term and the additional two-year-period over which the research term has been extended. We also received a \$4.0 million upfront payment from Novartis in July 2005 and an additional \$1.0 million payment in May 2007 to extend the research portion of the agreement. The amount of license fee revenue we recognized under our May 2005 research collaboration with Novartis decreased in 2009 and 2008, since we completed our research obligations in 2008. The amount of license fee revenue for Merck KGaA increased in 2009 reflecting a full year of involvement. We expect the license fee revenue we recognize from Merck KGaA and Merck & Co. to decrease in 2010 as we complete our research obligations under these agreements. As of December 31, 2009, we have \$7.3 million of deferred revenue under our Merck KGaA collaboration and \$4.7 million of deferred revenue under our Merck & Co. collaboration.

*Research and Development.* Research and development revenue increased by \$1.0 million in 2009 due to the reimbursement of clinical trial costs associated with the three clinical trials that we conducted under our collaboration agreement with Merck KGaA. This increase was offset by a decrease in revenue from research reimbursements under our collaboration with Merck & Co. as we had fewer employee expenses that were reimbursed under our collaboration with Merck & Co. We expect research and development revenue to be substantially lower in future periods because in September 2009, Merck KGaA assumed sponsorship of our ongoing Phase 1b clinical trials of IMO-2055. In addition, in March 2010, Merck KGaA assumed sponsorship of the Phase 1 clinical trial of IMO-2055 in healthy subjects. We will have no further responsibility for conducting clinical trials on behalf of Merck KGaA. However, the research term will continue until June 2010.

The \$1.8 million increase in research and development revenue in 2008 is due to clinical trial costs associated with the clinical trials that we conducted under our collaboration agreement with Merck KGaA in 2008, which expenses are reimbursed by Merck KGaA. The increase in 2008 is also attributable to the purchase of our bulk IMO-2055 drug supply by Merck KGaA at cost in 2008 and increased research costs attributable to expanding research under our Merck & Co. collaboration agreement, which costs are reimbursed by Merck & Co.

*Milestones.* Milestone revenue increased in 2009 as we earned milestone revenue of \$8.3 million under our collaboration with Merck KGaA relating to the dosing in January 2009 of the first patient in the clinical trial of IMO-2055 in patients with colorectal cancer and to the initiation in December 2009 of a Phase 2 clinical trial of IMO-2055 in patients with recurrent or metastatic squamous cell carcinoma of the head and neck. Our 2008 milestone revenue was attributable to \$1.0 million earned under our collaboration with Novartis relating to the initiation of a

Phase 1 clinical trial of QAX935 by Novartis and \$1.0 million earned under our collaboration with Merck & Co. relating to a preclinical milestone achieved by Merck & Co. with one of our novel TLR9 agonists used as an adjuvant in a cancer vaccine under preclinical study. In 2007, we also earned a \$0.3 million milestone under another collaboration agreement.

*Research and Development Expenses*

Research and development expenses increased by approximately \$2.4 million, or 15%, from \$16.2 million in 2008 to \$18.6 million in 2009 and increased by approximately \$3.0 million, or 23%, from \$13.2 million in 2007 to

**Table of Contents**

\$16.2 million in 2008. The increase in research and development expenses from 2008 to 2009 was primarily due to increased IMO-2055 clinical trial expenses associated with the three clinical trials that we conducted under our Merck KGaA agreement, which expenses are reimbursed by Merck KGaA, increased nonclinical safety studies and manufacturing of IMO-3100 in preparation for IMO-3100 clinical trials, and increased discovery research expenses. These increases were offset, in part, by a decrease in nonclinical safety studies and manufacturing of IMO-2125.

The increase in research and development expenses from 2007 to 2008 was primarily due to increased nonclinical safety studies and clinical costs associated with our ongoing clinical trial of IMO-2125 in HCV null responders, which we commenced in September 2007, increased costs for nonclinical safety studies associated with IMO-3100, increased research expenses under our Merck & Co. agreement, which Merck & Co. reimbursed, and increased IMO-2055 clinical trial expenses associated with the two clinical trials of IMO-2055 that we conducted under our Merck KGaA agreement, which Merck KGaA reimbursed. These increases were offset, in part, by decreases in expenses in 2008 related to our Phase 1 clinical trial of IMO-2055 combined with gemcitabine and carboplatin in patients with solid tumor cancers and to our Phase 2 Stage A clinical trial of IMO-2055 as a monotherapy in patients with metastatic or recurrent clear cell renal cancer, as we closed enrollment in both of these trials in 2007.

	Year Ended December 31,			Annual Percentage	
	2009	2008	2007	2009/2008	2008/2007
	(In millions)				
IMO-2055 external development expense	\$ 3.0	\$ 1.9	\$ 1.9	58%	
IMO-2125 external development expense	2.2	3.3	1.2	(33)%	175%
IMO-3100 external development expense	0.6				
Other drug development expense	5.6	4.5	4.5	24%	
Basic discovery expense	7.2	6.5	5.6	11%	16%
Total research and development expense	\$ 18.6	\$ 16.2	\$ 13.2	15%	23%

In the preceding table, research and development expense is set forth in the following five categories:

*IMO-2055 External Development Expenses.* IMO-2055 is being developed for cancer, excluding vaccines, under our collaboration with Merck KGaA. 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 payroll and overhead expenses. Since 2003, when we commenced clinical development of IMO-2055 and through December 31, 2009, we have incurred approximately \$17.4 million in external expenses in connection with IMO-2055.

Under our collaboration, Merck KGaA is responsible for all development of IMO-2055 for the treatment of cancer excluding vaccines. Merck KGaA agreed to reimburse us for costs associated with any trials that we initiated and conducted, including costs associated with the Phase 1b clinical trials of IMO-2055 in patients with non-small cell lung cancer and in patients with colorectal cancer and a Phase 1 clinical trial of IMO-2055 in healthy subjects, that were incurred after February 4, 2008, which is the date our agreement with Merck KGaA became effective. In September 2009, Merck KGaA assumed sponsorship of our ongoing Phase 1b clinical trials of IMO-2055. Merck KGaA is now the sponsor of all clinical trials of IMO-2055 for the treatment of cancer and has assumed responsibility for all further clinical development of IMO-2055 in the treatment of cancer, excluding vaccines. As a result, we expect expenses incurred by us for IMO-2055 development to be substantially lower in future periods.

IMO-2055 external development expenses increased by \$1.1 million, or 58%, from \$1.9 million in 2008 to \$3.0 million in 2009 and were consistent between 2007 and 2008. The increase from 2008 to 2009 was primarily attributable to increases in costs, which costs are reimbursed by Merck KGaA, associated with our Phase 1b clinical trials of IMO-2055 in patients with non-small cell lung cancer, which we initiated in December 2007, and IMO-2055 in patients with colorectal cancer, for which we commenced dosing in January 2009, and our Phase 1 clinical trial in healthy subjects that we initiated in April 2009. This increase was offset, in part, by a decrease in IMO-2055



## **Table of Contents**

expenses associated with our Phase 2 Stage A clinical trial in patients with metastatic or recurrent clear cell renal cancer which was completed in the second quarter of 2009.

In 2008, clinical trial expenses related to our Phase 1 clinical trial of IMO-2055 combined with gemcitabine and carboplatin chemotherapy in patients with solid tumor cancers and our Phase 2 Stage A clinical trial of IMO-2055 in patients with metastatic or recurrent clear cell renal cancer decreased from 2007 as we closed enrollment in 2007. This decrease was offset by increased clinical trial expenses in 2008 associated with the Phase 1b clinical trial of IMO-2055 in patients with non-small cell lung cancer, which we initiated in December 2007, as well as clinical trial expenses incurred in anticipation of the Phase 1b clinical trial of IMO-2055 in patients with colorectal cancer, for which we commenced dosing in January 2009.

In December 2007, we initiated a Phase 1b clinical trial of IMO-2055 in combination with Avastin and Tarceva, agents approved for the treatment of specific cancers, in patients with non-small cell lung cancer whose cancer had progressed during a prior course of standard therapy. We designed the trial to assess the safety of IMO-2055 in combination with standard dosages and schedules of Tarceva and Avastin and to determine the recommended dosage of IMO-2055 for potential use in a subsequent Phase 2 trial. In the trial, IMO-2055 was administered at four escalating dose levels of 0.08, 0.16, 0.32, and 0.48 mg/kg/week with fixed standard dose regimens of Avastin and Tarceva. Patients received IMO-2055 subcutaneously once a week, with each patient continuing to receive therapy until disease progression as determined by Response Evaluation Criteria in Solid Tumors, or RECIST, or another protocol-specified stopping criterion was met. In September 2009, we reported preliminary data from the dose-escalation portion of the trial. The combination of IMO-2055 with Avastin and Tarceva was well tolerated at all dose levels, and eight of the 16 patients enrolled in the dose-escalation portion of the trial remained on treatment for at least 18 weeks. Of the 13 patients evaluable for tumor response in the dose-escalation portion of the trial, three had a partial response and eight experienced stable disease. Based on the dose escalation portion of the trial, Merck KGaA selected a dose level of IMO-2055 for expanded patient recruitment to evaluate further the safety and pharmacokinetics of the combination.

In January 2009, we initiated a Phase 1b clinical trial of IMO-2055 in combination with Erbitux, a biological agent approved for treatment of certain cancers, and chemotherapy in patients with colorectal cancer whose cancer had progressed during a prior course of standard therapy. We designed the trial to assess the safety of the IMO-2055, Erbitux, and chemotherapy combination and to determine the recommended dosage of IMO-2055 for potential use in a subsequent Phase 2 clinical trial. This trial was designed with a target enrollment of up to 50 patients. Under the protocol for the trial, IMO-2055 is being administered at three escalating dose levels with fixed standard dose regimens of Erbitux and chemotherapy. Patients are receiving IMO-2055 subcutaneously once a week, with each patient continuing to receive therapy until disease progression, as determined by RECIST, or another protocol-specified stopping criterion is met.

In April 2009, we initiated on behalf of Merck KGaA a Phase 1 clinical trial of IMO-2055 monotherapy in healthy subjects. The Phase 1 healthy subjects trial was designed to characterize further the pharmacokinetic and pharmacodynamic profiles of IMO-2055 after single and multiple weekly subcutaneous and intravenous administrations. All scheduled patient visits were completed by June 2009.

Prior to entering our collaboration with Merck KGaA, we conducted three Phase 1 clinical trials and one Phase 2 clinical trial of IMO-2055. The Phase 1 clinical trials included a rising dose trial in healthy subjects, a rising dose trial in advanced cancer patients, and a combination trial of IMO-2055 with gemcitabine and carboplatin chemotherapy in advanced cancer patients. The Phase 2 clinical trial was a Phase 2 Stage A clinical trial of IMO-2055 monotherapy in patients with metastatic or recurrent clear cell renal cancer. The study contained four arms, comprised of a total of 89 treatment-naïve and second-line patients randomly assigned to receive IMO-2055 subcutaneously at either 0.16 mg/kg/week or 0.64 mg/kg/week. The primary objective of the study was tumor response based on RECIST.

Secondary objectives included time to progression, survival and safety. Progression-free survival was also analyzed. The primary objective was not achieved in the study. However, the median progression-free survival was 4.5 months and 1.9 months for the 0.16- and 0.64-mg/kg/week treatment-naïve patients, and 3.4 months and 4.3 months for the 0.16- and 0.64-mg/kg/week second-line patients. The median overall survival was 23.5 months over all arms and 58% of patients had stable disease. Two patients (one second-line and one treatment-naïve, and each receiving 0.64 mg/kg/week) had confirmed partial responses, and seven

## **Table of Contents**

patients received weekly IMO-2055 treatment for at least one year. IMO-2055 treatment was generally well-tolerated with good dose intensity in all arms of the study.

Approximately \$2.9 million and \$1.0 million of expenses in 2009 and 2008, respectively, related to the Phase 1b clinical trial in patients with non-small cell lung cancer, the Phase 1b clinical trial in patients with colorectal cancer and the Phase 1 clinical trial in healthy subjects, which expenses are reimbursed by Merck KGaA.

*IMO-2125 External Development Expenses.* These expenses include external expenses that we have incurred in connection with IMO-2125, our lead compound that we are developing for chronic HCV infection. 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 \$6.7 million in external development expenses through December 31, 2009, including costs associated with our Phase 1 clinical trials and related nonclinical studies and manufacturing and related process development.

External development expenses for IMO-2125 decreased by \$1.1 million, or 33%, from \$3.3 million in 2008 to \$2.2 million in 2009. The decrease in IMO-2125 expenses in 2009 compared to 2008 was primarily attributable to higher manufacturing costs in 2008 associated with producing IMO-2125 in anticipation of our Phase I clinical trials and a decrease in costs for nonclinical safety studies of IMO-2125, which decreased because a lower level of nonclinical safety and manufacturing activity was required to support the clinical trials ongoing during 2009. This decrease was partially offset by an increase in costs related to our Phase 1 clinical trial to assess the safety of IMO-2125 in combination with ribavirin in treatment-naïve HCV patients, which we initiated in October 2009. External development expenses for IMO-2125 increased by \$2.1 million, or 175%, from \$1.2 million in 2007 to \$3.3 million in 2008. The increase in IMO-2125 expenses in 2008 compared to 2007 was primarily attributable to manufacturing IMO-2125, our Phase 1 clinical trial of IMO-2125 in null responder HCV patients, which we commenced in September 2007, and costs for nonclinical safety studies of IMO-2125 initiated after the May 2007 submission to the United States Food and Drug Administration, or FDA, of the IMO-2125 Investigational New Drug, or IND, application.

In May 2007, we submitted an IND application for IMO-2125 to the FDA. In September 2007, we initiated a Phase 1 clinical trial of IMO-2125 in patients with genotype 1 chronic HCV infection who had no response to a prior regimen of the current standard of care therapy. We refer to these patients as null responder HCV patients. The clinical trial is currently being conducted at six sites in the United States. In the trial, we are enrolling cohorts of ten patients at escalating IMO-2125 dose levels. To date, we have enrolled patients in four cohorts, evaluating IMO-2125 at 0.04 mg/kg/week, 0.08 mg/kg/week, 0.16 mg/kg/week and 0.32 mg/kg/week. Based on interim results from these cohorts, we extended the trial to a fifth dose level and are currently enrolling patients in a fifth cohort at 0.48 mg/kg/week. Of the ten patients in a cohort, eight are randomized to receive IMO-2125 treatment and two are randomized to receive placebo treatment. Patients receive a single dose of IMO-2125 or placebo once per week by subcutaneous injection for four weeks. The primary objective of the trial is to assess the safety of IMO-2125 at each dose level. We are also evaluating the effects of IMO-2125 on HCV RNA levels and on immune system activation in this trial.

In December 2009, we announced interim results from null responder HCV patients treated through the originally planned four cohorts of this trial. IMO-2125 was well tolerated by all patients in the four cohorts. IMO-2125-treated patients showed dose-dependent increases in natural interferon-alpha and other antiviral proteins including interferon-inducible protein 10 and 2,5'-oligoadenylate synthetase. In addition, an increasing percentage of patients, ranging from 40% at the 0.08 mg/kg/week dose level to 75% at the 0.32 mg/kg/week dose level, achieved a maximum reduction in viral load of 1 log<sub>10</sub> or more at least once during the four-week treatment period. In contrast, none of the patients who received placebo treatment or IMO-2125 at the 0.04-mg/kg/week dose level achieved a maximum

reduction in viral load of 1 log<sub>10</sub> or greater at any time during the four-week treatment period. We plan to present detailed interim results of the trial at a scientific meeting in the second quarter of 2010.

In addition to the on-going Phase 1 clinical trial of IMO-2125 in null responder HCV patients, we are conducting a Phase 1 clinical trial of IMO-2125 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

**Table of Contents**

genotype 1 chronic HCV infection. We initiated the trial in October 2009. In this clinical trial, patients will receive IMO-2125 or a control article by subcutaneous injection once per week for four weeks at escalating dose levels in combination with daily oral administration of standard doses of ribavirin. A total of 15 patients are planned for the first cohort, with 12 randomized to receive IMO-2125 and ribavirin and three randomized to receive placebo and ribavirin as the control. Starting with the second cohort, 12 patients will be randomized to receive IMO-2125 and ribavirin and six patients will be randomized to receive pegylated recombinant alfa-2a interferon and ribavirin as the control. The primary objective of the trial is to assess the safety and tolerability of IMO-2125 in combination with ribavirin. In addition, we plan to monitor the effect of treatment on HCV RNA levels. The clinical trial is currently being conducted at sites in France and Russia.

Following the completion of our Phase 1 study in null responder HCV patients, we plan to initiate in the second half of 2010 a clinical trial in null responders in which patients will receive IMO-2125 in combination with ribavirin for 12 weeks. With the data from this trial, together with the data from the two Phase 1 clinical trials, we plan to determine the next steps in the clinical development of IMO-2125 for HCV infection. As a result, we expect IMO-2125 external development expenses to increase in 2010.

*IMO-3100 External Development Expenses.* These expenses include external expenses that we have incurred in connection with IMO-3100, our lead TLR7/TLR9 antagonist drug candidate, 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 \$0.6 million in external development expenses through December 31, 2009, including costs associated with the start-up of our Phase 1 clinical trial of IMO-3100 in healthy subjects and manufacturing and related process development.

In the fourth quarter of 2009, we submitted to the FDA an IND application for the clinical evaluation of IMO-3100 in autoimmune diseases. In January 2010, we initiated a Phase 1 clinical trial of IMO-3100 in healthy subjects. In this rising single-dose Phase 1 trial, IMO-3100 is being administered by subcutaneous injection. The primary objective is to evaluate safety and tolerability of IMO-3100. Secondary objectives are to characterize the pharmacokinetic profile of IMO-3100 and to assess the pharmacodynamic mechanism of action through measurement of the response of PBMCs to TLR7 and TLR9 agonists. The trial is being conducted at a single U.S. site.

We plan to use the results from this rising single-dose clinical trial to select dosages for an anticipated follow-up trial in healthy subjects. The purpose of the second Phase 1 trial would be to evaluate the safety, pharmacokinetics and pharmacodynamic mechanism of action of IMO-3100 with escalating doses in a study involving the subcutaneous administration of IMO-3100 once per week for four weeks. We intend to identify an initial autoimmune disease indication for further clinical development of IMO-3100 by the end of 2010.

*Other Drug Development Expenses.* These expenses include internal and external expenses associated with preclinical development of identified compounds in anticipation of advancing these compounds into clinical development in addition to internal costs associated with products in clinical development.

The internal and 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, as well as payroll and overhead. The internal expenses associated with products in clinical development include costs associated with our Hepatitis C Clinical Advisory Board, our Oncology Clinical Advisory Board, our Autoimmune Disease Scientific Advisory Board, payroll and overhead.

The increase in 2009 from 2008 was primarily due to increases in manufacturing and other pre-IND direct external expenses, including nonclinical safety studies, related to IMO-3100 that we incurred through November 2009 when we submitted the IND for IMO-3100 to the FDA. Other drug development expenses were consistent between 2007 and 2008. In 2008, we had a decrease from 2007 in other drug development expenses attributable to lower payroll expenses resulting from fewer full-time equivalent positions associated with and allocated to preclinical and clinical development and a decrease in IMO-2125 expenses due to attribution of IMO-2125 expenses incurred after the commencement of clinical development in May 2007 to the IMO-2125 external development expense category shown separately above. This decrease between 2007 and 2008 in other drug

## **Table of Contents**

development expenses in 2008 was partially offset by increased costs associated with nonclinical safety studies associated with IMO-3100 and other compounds during 2008.

*Basic Discovery Expenses.* These expenses include our internal and external expenses relating to discovery research in our TLR-targeted programs, including TLR7, 8, and 9 agonists, TLR7/9 antagonists, and TLR antisense compounds. These expenses reflect payments for laboratory supplies, external research, and professional fees, as well as payroll and overhead. Basic discovery expenses increased by \$0.7 million, or 11%, from \$6.5 million in 2008 to \$7.2 million in 2009 and increased by \$0.9 million, or 16%, from \$5.6 million in 2007 to \$6.5 million in 2008. The increase in 2009 as compared to 2008 was primarily attributable to an increase in laboratory supply costs and allocated facility costs and higher stock-based compensation for employees. The increase in expense in 2008 compared to 2007 was primarily attributable to an increase in payroll expenses, including higher stock-based compensation for employees, laboratory supply costs and allocated costs relating to work under our Merck & Co. collaboration.

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 our ongoing clinical trials 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 \$1.2 million, or 12%, from \$9.8 million in 2008 to \$8.6 million in 2009 and increased by approximately \$0.1 million, or 1%, from \$9.7 million in 2007 to \$9.8 million in 2008. General and administrative expenses consist primarily of salary expense, stock compensation expense, consulting fees and professional legal fees associated, in part, with our patent applications and maintenance, our regulatory filing requirements, and business development.

The \$1.2 million decrease from 2008 to 2009 was primarily due to lower consulting fees and lower external patent expenses and stock-based compensation for consultants in 2009. This decrease was offset by increased employee costs in this area, including higher stock-based compensation expense for employees. The \$0.1 million increase from 2007 to 2008 primarily reflects higher employee stock compensation expense, higher consulting fees associated with corporate business strategic initiatives undertaken in 2008 and higher patent filing and preparation costs. The increase in stock compensation expense was \$569,000 in the year ended December 31, 2008 and was primarily the result of stock compensation expenses associated with employee stock options granted in 2008 when our stock price was higher than in previous years. These increases were offset, in part, by lower corporate legal expenses, lower payroll expenses as a result of our former President's resignation at the end of 2007 and no 2008 costs related to the transition agreement entered into with our former Chief Financial Officer in May 2007.

### *Investment Income, Net*

Investment income decreased by approximately \$1.2 million, or 92%, from \$1.3 million in 2008 to \$0.1 million in 2009 and decreased by approximately \$0.4 million, or 24%, from \$1.7 million in 2007 to \$1.3 million in 2008. These decreases are primarily attributable to lower interest rates on our money market funds, lower yields on our investments, and lower average funds earning interest during 2009.

*Interest Expense*

Interest expense was negligible in 2009 and was consistent from 2007 to 2008. Interest expense in 2008 reflected interest through our March 2008 repayment in full of our note payable to General Electric Capital Corporation, or GE, and a prepayment premium associated with the note repayment. As a result of our repayment, the note was cancelled. Interest expense in 2007 reflected interest through February 20, 2007 related to our 4% notes, issued in May 2005, which were converted in the aggregate principal amount of approximately



## **Table of Contents**

\$5,033,000 into 706,844 shares of common stock on February 20, 2007 and interest expense associated with our note payable to GE.

### *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. During 2008, we recorded a tax benefit of approximately \$24,000 which was primarily related to refundable research and experimental tax credits. We did not have income subject to the alternative minimum tax for the years ended December 31, 2008 and 2007.

### *Foreign Currency Exchange Loss*

Foreign currency exchange loss was negligible in 2009 and \$0.3 million in 2008. In February 2008, Merck KGaA paid us a \$40.0 million upfront license fee denominated in Euros. We received \$39.7 million U.S. dollars due to foreign currency exchange rates in effect at the time we received the payment, which resulted in the foreign currency exchange loss. There was no foreign currency exchange loss for the year ended 2007.

### *Net Income (Loss)*

As a result of the factors discussed above, we had net income of \$7.5 million and \$1.5 million for the years ended December 31, 2009 and 2008, respectively, compared to a net loss of \$13.2 million for the year ended December 31, 2007. We have incurred losses of \$73.5 million since January 1, 2001. We incurred net losses of \$260.2 million prior to December 31, 2000 during which time we were involved in the development of antisense technology. Since our inception, we had an accumulated deficit of \$333.7 million through December 31, 2009. We may incur substantial operating losses in future periods.

### *Net Operating Loss Carryforwards*

As of December 31, 2009, we had cumulative net operating loss carryforwards, or NOLs, of approximately \$249.3 million and \$30.9 million available to reduce federal and state taxable income which expire through 2029 and 2014, respectively. In addition, we had cumulative federal and state tax credit carryforwards of \$5.4 million and \$4.6 million, respectively, available to reduce federal and state income taxes, which expire through 2029 and 2024, 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, 2009, have resulted in ownership changes in excess of 50% and that will significantly limit our ability to utilize our NOL and tax credit carryforwards. As a result of this ownership change, we estimate that between 30% and 45% of the \$249.3 million in federal NOLs could be utilized to offset federal taxable income and approximately 66% of the \$5.4 million of federal tax credit carryforwards could be used to offset federal income taxes. 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, to make capital expenditures and to pay debt service. Historically, we have funded our cash requirements primarily through the following:

equity and debt financing;

license fees and research funding under collaborative and license agreements;

interest income; and

lease financings.

**Table of Contents**

During 2009, we received total proceeds of \$0.3 million from purchases made under our employee stock purchase plan and stock option exercises. During 2008, we received total proceeds of \$10.0 million from warrant exercises, including the exercises of the August 2004 Warrants and the May 2005 Warrant discussed below, stock option exercises and purchases under our employee stock purchase plan.

In June 2008, we sent notice to the holder of a warrant to purchase 70,684 shares of our common stock that was issued in May 2005 with an expiration date of May 24, 2010, or the May 2005 Warrant, that under the terms of the warrant agreement, we intended to redeem on September 12, 2008 the May 2005 Warrant if not exercised as of that date for a redemption price of \$0.08 per share of common stock underlying the May 2005 Warrant. We were entitled to exercise this redemption right because the closing price of our common stock for twenty consecutive trading days ending June 3, 2008 was greater than \$14.24 or 200% of the exercise price of the warrant. The May 2005 Warrant was exercisable by cash payment only and had an exercise price of \$7.12 per share of common stock. Following the June 2008 notice of redemption, we received approximately \$503,000 in proceeds from the exercise of the May 2005 Warrant to purchase 70,684 shares of our common stock. The May 2005 Warrant was exercised in September 2008.

In January 2008, we sent notice to holders of warrants to purchase our common stock that were issued in August 2004 with an expiration date of August 27, 2009, or the August 2004 Warrants, that under the terms of the warrant agreement, we intended to redeem on March 31, 2008 any August 2004 Warrants not exercised as of that date for a redemption price of \$0.08 per share of common stock underlying the August 2004 Warrants. We were entitled to exercise this redemption right because the closing price of our common stock for twenty consecutive trading days ending December 20, 2007 was greater than \$10.72 or 200% of the exercise price of the warrant. The August 2004 Warrants were exercisable by cash payment only and had an exercise price of \$5.36 per share of common stock. Following the January 2008 notice of redemption and through March 31, 2008, we received approximately \$1.5 million in proceeds from the exercise of August 2004 Warrants to purchase 274,650 shares of common stock. As of December 31, 2008, all August 2004 Warrants had been exercised in full.

As of December 31, 2009, there are outstanding warrants to purchase 1,704,545 shares of common stock at an exercise price of \$5.20 and warrants to purchase 761,718 shares of common stock at an exercise price of \$5.92 per share. These warrants were issued in September 2006 and expire on September 24, 2011.

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 the treatment of cancer, excluding cancer vaccines. 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. Since entering this agreement, we have earned \$8.3 million in milestone payments of which we received \$8.1 million due to foreign currency exchange rates in effect at the time of payment and have been or are being reimbursed \$4.5 million for expenses related to the development of IMO-2055. Approximately \$4.1 million of the \$8.3 million in milestone revenue recorded in 2009 was received in 2010.

In June 2007, we executed a promissory note in the aggregate principal amount of \$1.3 million in favor of GE. The promissory note was secured by specific laboratory, manufacturing, office and computer equipment and was subject to the terms of a master security agreement between us and GE. The promissory note bore interest at a fixed rate of 11% per annum, and was payable in 48 consecutive monthly installments of principal and accrued interest, with the first installment having been paid out of the proceeds of the borrowing. In March 2008, we paid approximately \$1.2 million to GE as payment in full of all obligations outstanding under our promissory note with GE. The payment represented approximately \$1.1 million of principal amount outstanding plus accrued interest through the date of payment and a prepayment premium of approximately \$0.1 million. Upon payment, the note was cancelled.

In December 2006, we entered into an exclusive license and research collaboration agreement with Merck & Co. 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, Merck & Co. paid us a \$20.0 million license fee in December 2006. In addition, in connection with the execution of the license and collaboration agreement, we issued and sold to Merck & Co. 1,818,182 shares of our common stock for a price of

## **Table of Contents**

\$5.50 per share resulting in an aggregate purchase price of \$10.0 million. Since entering this agreement, we have received \$1.0 million in milestone payments and \$3.4 million in research and development payments.

### *Cash Flows*

As of December 31, 2009, we had approximately \$40.2 million in cash and cash equivalents and investments, a net decrease of approximately \$15.4 million from December 31, 2008. 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 \$333.7 million at December 31, 2009. We may 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.

We had cash, cash equivalents, and investments of \$40.2 million at December 31, 2009. We believe that our existing cash, cash equivalents, and investments will be sufficient to fund our operations at least through December 31, 2011 based on our current operating plan, which assumes that we will continue to conduct our three ongoing clinical trials and that we will conduct the 12-week Phase 1b clinical trial of IMO-2125 in null responder HCV patients and the 4-week Phase 1 clinical trial of IMO-3100 in healthy subjects that we plan to initiate in 2010 but does not assume that we will conduct any other clinical trials. We will need to raise additional funds to operate our business beyond such date. However, if we elect to conduct additional clinical trials beyond our ongoing clinical trials and the planned IMO-2125 and IMO-3100 trials, we may need to raise funds prior to such date.

We may 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 success of our clinical and preclinical development programs;

the success of our existing strategic collaborations with Merck KGaA and Merck & Co.;

the cost, timing and outcome of regulatory reviews;

**Table of Contents**

the receptivity of the capital markets to financings by biotechnology companies; 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, 2009, our contractual commitments were as follows:

<b>Contractual Obligations</b>	<b>Total</b>	<b>Payments Due by Period</b>			<b>After 5 years</b>
		<b>Less than 1 year</b>	<b>1-3 years</b>	<b>3-5 years</b>	
		<b>(In thousands)</b>			
Operating lease commitments	\$ 6,282	\$ 1,346	\$ 2,827	\$ 2,109	\$
Capital lease commitments	28	19	9		
<b>Total</b>	<b>\$ 6,310</b>	<b>\$ 1,365</b>	<b>\$ 2,836</b>	<b>\$ 2,109</b>	<b>\$</b>

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 specified milestones and to pay royalties to our licensors. These contingent milestone and royalty payment obligations are not included in the above table. As of December 31, 2009, we had no off balance sheet arrangements. We do not expect to make any material capital expenditures in 2010.

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

As of December 31, 2009, we had a recorded receivable of 3.0 million Euros, or \$4.3 million, and a prepaid expense relating to contract research organization services for our Phase 1 clinical trial of IMO-2125 in combination currently being conducted at sites in France and Russia of 0.1 million Euros, or \$0.1 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.



**Table of Contents****Item 8. Financial Statements and Supplementary Data.**

All financial statements required to be filed hereunder are filed as listed under Item 15(a) and are incorporated herein by this reference.

**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, 2009. 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.

	Dec. 31, 2009	Sep. 30, 2009	Jun. 30, 2009	Three Months Ended			Jun. 30, 2008	Mar. 31, 2008
				Mar. 31, 2009	Dec. 31, 2008	Sep. 30, 2008		
	(In thousands, except per share data)							
<b>Statement of Operations Data:</b>								
Alliance revenues	\$ 10,180	\$ 6,538	\$ 11,497	\$ 6,303	\$ 6,274	\$ 7,517	\$ 7,876	\$ 4,783
Operating expenses:								
Research and development	4,391	4,288	5,413	4,478	4,286	3,580	3,752	4,534
General and administrative	2,070	2,210	2,133	2,148	1,805	2,323	3,243	2,427
Total operating expenses	6,461	6,498	7,546	6,626	6,091	5,903	6,995	6,961
Income (loss) from operations	3,719	40	3,951	(323)	183	1,614	881	(2,178)
Investment income	23	20	31	71	159	369	410	406
Interest expense	(3)				(2)	(3)	(5)	(82)
Foreign currency exchange loss	(21)	(6)						(267)
Income (loss) before income taxes	3,718	54	3,982	(252)	340	1,980	1,286	(2,121)
Income tax benefit (provision)	214	(30)	(140)		24		50	(50)
Net income (loss)	\$ 3,932	\$ 24	\$ 3,842	\$ (252)	\$ 364	\$ 1,980	\$ 1,336	\$ (2,171)
	\$ 0.17		\$ 0.16	\$ (0.01)	\$ 0.02	\$ 0.09	\$ 0.06	\$ (0.10)

Basic net income (loss) per common share								
Diluted net income (loss) per common share	\$ 0.17		\$ 0.16	\$ (0.01)	\$ 0.01	\$ 0.08	\$ 0.05	\$ (0.10)
Shares used in computing basic income (loss) per common share(1)	23,452	23,441	23,407	23,379	23,331	23,022	22,481	21,899
Shares used in computing diluted income (loss) per common share(1)	23,808	24,341	23,956	23,379	24,822	25,779	25,507	21,899

(1) Computed on the basis described in Note 13 of notes to financial statements appearing elsewhere in this Annual Report on Form 10-K.

**Table of Contents**

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

None.

**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, 2009. 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, 2009, 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, 2009. 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, 2009, 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.

**Table of Contents**

**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, 2009, 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, 2009, 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, 2009 and 2008, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2009 of Idera Pharmaceuticals, Inc. and our report dated March 10, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts  
March 10, 2010

**Table of Contents**

**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, 2009 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 in June 2010.

**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](http://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](http://www.iderapharma.com).

The remainder of the response to this item is contained under the following captions in the 2010 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 2010 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 2010 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 compensations plans are contained in the 2010 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 2010 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 2010 Proxy Statement under the caption Independent Registered Public Accounting Firm Fees, which section is incorporated herein by reference.



**Table of Contents**

**PART IV.**

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

(a) (1) *Financial Statements.*

	<b>Page number in this Report</b>
Report of Independent Registered Public Accounting Firm	F-2
Balance Sheets at December 31, 2009 and 2008	F-3
Statements of Operations for the years ended December 31, 2009, 2008 and 2007	F-4
Statements of Stockholders' Equity for the years ended December 31, 2009, 2008 and 2007	F-5
Statements of Cash Flows for the years ended December 31, 2009, 2008 and 2007	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.

**Table of Contents****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 10th day of March 2010.

Idera Pharmaceuticals, Inc.

By: /s/ Sudhir Agrawal  
Sudhir Agrawal  
*President, Chief Executive Officer  
and Chief Scientific 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.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ James B. Wyngaarden James B. Wyngaarden, M.D.	Chairman of the Board of Directors	March 10, 2010
/s/ Sudhir Agrawal Sudhir Agrawal, D. Phil.	President, Chief Executive Officer, Chief Scientific Officer and Director (Principal Executive Officer)	March 10, 2010
/s/ Louis J. Arcudi, III Louis J. Arcudi III	Chief Financial Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)	March 10, 2010
/s/ Youssef El Zein Youssef El Zein	Director	March 10, 2010
/s/ C. Keith Hartley C. Keith Hartley	Director	March 10, 2010
/s/ Robert W. Karr Robert W. Karr, M.D.	Director	March 10, 2010
/s/ Malcolm MacCoss Malcolm MacCoss, Ph.D.	Director	March 10, 2010
/s/ Hans Mueller	Director	March 10, 2010

Hans Mueller, Ph.D.

/s/ William S. Reardon

Director

March 10, 2010

William S. Reardon, C.P.A.

/s/ Alison Taunton-Rigby

Director

March 10, 2010

Alison Taunton-Rigby, Ph.D., OBE

**IDERA PHARMACEUTICALS, INC.**

**INDEX TO FINANCIAL STATEMENTS**

**December 31, 2009**

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Balance Sheets</u>	F-3
<u>Statements of Operations</u>	F-4
<u>Statements of Stockholders' Equity</u>	F-5
<u>Statements of Cash Flows</u>	F-6
<u>Notes to Financial Statements</u>	F-7

F-1

---

**Table of Contents**

**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, 2009 and 2008, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2009. 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, 2009 and 2008, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2009, 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, 2009, 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 10, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts  
March 10, 2010

**Table of Contents****IDERA PHARMACEUTICALS, INC.****BALANCE SHEETS**

<b>(In thousands, except per share amounts)</b>	<b>December 31, 2009</b>	<b>December 31, 2008</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 25,471	\$ 45,165
Short-term investments	6,270	10,441
Receivables	4,497	474
Prepaid expenses and other current assets	1,030	876
Total current assets	37,268	56,956
Property and equipment, net	1,387	1,824
Non-current portion of prepaid expenses	104	104
Long-term investments	8,466	
Restricted cash, net of current portion	414	516
Total assets	\$ 47,639	\$ 59,400
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,166	\$ 1,345
Accrued expenses	931	1,199
Current portion of capital lease	19	18
Current portion of deferred revenue	12,098	22,295
Total current liabilities	14,214	24,857
Capital lease obligation, net of current portion	9	31
Deferred revenue, net of current portion	67	12,165
Other liabilities	244	180
Total liabilities	14,534	37,233
Commitments and contingencies		
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 at December 31, 2009 and 2008		

Edgar Filing: IDERA PHARMACEUTICALS, INC. - Form 10-K

Common stock, \$0.001 par value, Authorized 70,000 shares at December 31, 2009 and 2008 Issued and outstanding 23,479 and 23,413 shares at December 31, 2009 and 2008, respectively	23	23
Additional paid-in capital	366,780	363,405
Accumulated deficit	(333,679)	(341,225)
Accumulated other comprehensive loss	(19)	(36)
Total stockholders' equity	33,105	22,167
Total liabilities and stockholders' equity	\$ 47,639	\$ 59,400

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

F-3

---

**Table of Contents****IDERA PHARMACEUTICALS, INC.****STATEMENTS OF OPERATIONS**

<b>(In thousands, except per share amounts)</b>	<b>Years Ended December 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
Alliance revenue	\$ 34,518	\$ 26,450	\$ 8,124
Operating expenses:			
Research and development	18,570	16,152	13,195
General and administrative	8,561	9,798	9,656
Total operating expenses	27,131	25,950	22,851
Income (loss) from operations	7,387	500	(14,727)
Other income (expense):			
Investment income, net	145	1,344	1,668
Interest expense	(3)	(92)	(149)
Foreign currency exchange loss	(27)	(267)	
Income (loss) before income taxes	7,502	1,485	(13,208)
Income tax benefit	44	24	
Net income (loss)	\$ 7,546	\$ 1,509	\$ (13,208)
Income (loss) per common share (Note 13):			
Basic	\$ 0.32	\$ 0.07	\$ (0.62)
Diluted	\$ 0.31	\$ 0.06	\$ (0.62)
Shares used in computing basic income (loss) per common share	23,420	22,655	21,221
Shares used in computing diluted income (loss) per common share	24,079	25,331	21,221

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



**Table of Contents****IDERA PHARMACEUTICALS, INC.****STATEMENTS OF STOCKHOLDERS EQUITY**

(In thousands)	Common Stock \$0.001		Additional	Accumulated Other		Total Stockholders Equity
	Number of Shares	Par Value	Paid-In Capital	Accumulated Deficit	Comprehensive (Loss)/Income	
<b>Balance, December 31, 2006</b>	20,458	\$ 20	\$ 341,743	\$ (329,526)	\$	\$ 12,237
Exercise of common stock options, warrants and employee stock purchases	334	1	1,769			1,770
Issuance of stock for services	7		44			44
Conversion of notes	707	1	4,766			4,767
Non-employee stock option expense			519			519
Stock-based compensation	63		1,582			1,582
Comprehensive income (loss):						
Unrealized gain on marketable securities					8	8
Net loss				(13,208)		(13,208)
Total comprehensive loss						(13,200)
<b>Balance, December 31, 2007</b>	21,569	\$ 22	\$ 350,423	\$ (342,734)	\$ 8	\$ 7,719
Exercise of common stock options, warrants and employee stock purchases	1,849	1	10,029			10,030
Issuance of stock for services	2		22			22
Non-employee stock option expense			398			398
Stock-based compensation			2,628			2,628
Repurchase of common stock	(7)		(95)			(95)
Comprehensive income (loss):						
Unrealized loss on marketable securities					(44)	(44)
Net income				1,509		1,509
Total comprehensive income						1,465
<b>Balance, December 31, 2008</b>	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 stock for services	3		17			17
			9			9

Non-employee stock option expense						
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
<b>Balance, December 31, 2009</b>	23,479	\$ 23	\$ 366,780	\$ (333,679)	\$ (19)	\$ 33,105

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

**Table of Contents****IDERA PHARMACEUTICALS, INC.****STATEMENTS OF CASH FLOWS**

<b>(In thousands)</b>	<b>Years Ended December 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
<b>Cash Flows from Operating Activities:</b>			
Net income (loss)	\$ 7,546	\$ 1,509	\$ (13,208)
Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities			
Loss from disposition of assets		2	6
Non-employee stock option expense	9	398	519
Stock-based compensation	3,093	2,628	1,582
Issuance of stock for services	17	22	44
Amortization expense	40	36	(46)
Depreciation expense	563	530	364
Amortization of deferred financing costs			31
Changes in operating assets and liabilities			
Receivables	(4,023)	(181)	(230)
Prepaid expenses and other current assets	(154)	218	(264)
Accounts payable, accrued expenses, and other liabilities	(383)	(273)	899
Deferred revenue	(22,295)	18,675	(5,457)
Net cash (used in) provided by operating activities	(15,587)	23,564	(15,760)
<b>Cash Flows from Investing Activities:</b>			
Purchases of available-for-sale securities	(14,768)	(22,985)	(50,545)
Proceeds from sale of available-for-sale securities			37,814
Proceeds from maturities of available-for-sale securities	10,450	23,620	15,220
Decrease in restricted cash	102		
Purchases of property and equipment	(126)	(393)	(1,632)
Net cash (used in) provided by investing activities	(4,342)	242	857
<b>Cash Flows from Financing Activities:</b>			
Net proceeds from issuance of note payable			1,278
Payments on notes payable		(1,143)	(135)
Proceeds from exercise of common stock options, warrants and employee stock purchases	297	10,030	1,770
Repurchases of common stock	(41)	(95)	
Payments on capital lease	(21)	(21)	(18)
Net cash provided by financing activities	235	8,771	2,895
Net (decrease) increase in cash and cash equivalents	(19,694)	32,577	(12,008)
Cash and cash equivalents, beginning of period	45,165	12,588	24,596
Cash and cash equivalents, end of period	\$ 25,471	\$ 45,165	\$ 12,588

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

F-6

---

**Table of Contents**

**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS**  
**December 31, 2009**

**(1) Organization**

Idera Pharmaceuticals, Inc. ( Idera or the Company ) is a biotechnology company engaged in the discovery and development of DNA- and RNA-based drug candidates targeted to Toll-Like Receptors, or TLRs, to treat infectious diseases, autoimmune and inflammatory diseases, cancer, and asthma and allergies, and for use as vaccine adjuvants. Drug candidates are compounds that the Company is developing and that have not been approved for any commercial use. TLRs are specific receptors present in immune system cells that recognize the DNA or RNA of bacteria or viruses and initiate an immune response. Relying on its expertise in DNA and RNA chemistry, the Company has designed and created proprietary TLR agonists and antagonists to modulate immune responses. 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.

Idera's business strategy is to advance applications of its TLR-targeted drug candidates in multiple disease areas simultaneously. The Company is advancing some of these applications through internal programs, and it seeks to advance other applications through collaborative alliances with pharmaceutical companies. Collaborators provide the necessary resources and drug development experience to advance the Company's compounds in their programs. Upfront payments and milestone payments received from collaborations help to provide the Company with the financial resources for its internal research and development programs.

The Company's internal programs are focused on developing TLR-targeted drug candidates for the potential treatment of infectious diseases, autoimmune and inflammatory diseases, cancer, and asthma and allergies.

In addition to its internal programs, the Company is currently collaborating with two pharmaceutical companies to advance other applications of its TLR-targeted compounds. The Company is collaborating with Merck KGaA for cancer treatment, excluding cancer vaccines, and with Merck & Co., Inc., or Merck & Co., for vaccine adjuvants in the fields of cancer, infectious diseases, and Alzheimer's disease. Merck KGaA and Merck & Co. are not related.

At December 31, 2009, the Company had an accumulated deficit of \$333.7 million. The Company may incur substantial operating losses in future periods. The Company does not expect to generate significant funds until it successfully completes development and obtains marketing approval for products, either alone or in collaborations with third parties, which it expects will take a number of years. In order to commercialize its products, the Company needs to address a number of technological challenges and to comply with comprehensive regulatory requirements. In 2010, the Company expects that its research and development expenses will be higher than its research and development expenses in 2009 as it expands its clinical trials and accelerates its early-stage programs on TLR antagonists and on agonists of TLR7 and TLR8.

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.

F-7

---

**Table of Contents**

**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, 2009 and 2008 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 loss 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. The Company had no held-to-maturity investments at either December 31, 2009 or 2008. 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 2009, 2008 or 2007. There were no losses or other-than-temporary declines in value included in investment income, net for any securities for the years ended December 31, 2009, 2008 and 2007. The Company had no auction rate securities as of December 31, 2009 and 2008.

*(d) Restricted Cash*

As part of the lease arrangement entered into by the Company in October 2006 to lease its office and laboratory facility commencing in June 2007, (see Note 10(a)), the Company was required to restrict \$619,000 of cash for a security deposit. The restricted cash was reduced by approximately \$102,000 in June 2009 upon the second anniversary of the lease commencement date. As a result, at December 31, 2009 restricted cash was \$516,000, including \$102,000 classified in other current assets. The restricted cash is held in certificates of deposit securing a line of credit for the lessor. The restricted cash is expected to be further reduced by approximately \$102,000 upon each of the third and fourth anniversaries of the lease commencement, subject to certain conditions.

*(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 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.



**Table of Contents****IDERA PHARMACEUTICALS, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

Under the Company's existing collaborative arrangements, the Company is generally entitled to receive non-refundable license fees, milestone payments, reimbursements of internal and external research and development expenses and patent-related expenses and 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. Revenue recognized under the Company's collaborative arrangements is as follows for the years ended December 31, 2009, 2008 and 2007:

<b>(In thousands)</b>	<b>December 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
Merck KGaA	\$ 28,558	\$ 16,921	\$
Merck & Co.	5,826	7,458	6,078
Novartis	19	1,861	1,420
Other			250
Total collaboration revenue	34,403	26,240	7,748
Other revenue	115	210	376
Total alliance revenue	\$ 34,518	\$ 26,450	\$ 8,124

During the years ended December 31, 2009, 2008 and 2007, the Company incurred approximately \$3,024,000, \$1,778,000, and \$148,000, respectively, in third-party expenses in connection with its collaborative arrangements. These third party expenses are classified as research and development and general and administrative expenses in the Company's statement of operations.

When evaluating multiple element arrangements, the Company considers whether the components of the arrangement represent separate units of accounting.

The Company recognizes 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 arrangement. If the estimated period of continuing involvement is subsequently modified, the period over which the upfront fee is recognized is modified, accordingly, on a prospective basis.

The Company recognizes revenue from reimbursements earned in connection with its research and development collaboration agreements as related research and development costs are incurred, and its 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 trade accounts receivable 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 specifically associated with a separate earnings process, the Company recognizes revenue when the specific performance obligation is completed. Performance obligations typically consist 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 recognizes revenue from milestone payments received under collaboration agreements when earned, provided that the milestone event is substantive, its achievability was not reasonably assured at the inception of the agreement, it has no further performance obligations relating to the event and collectability is reasonable assured. 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 is due.

F-9

---

**Table of Contents**

**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

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, in connection with its existing collaboration agreements, the Company has recorded on its balance sheet short-term and long-term deferred revenue based on its best estimate of when such revenue will be recognized. However, this estimate is based on the Company's collaboration agreements and its current operating plan and, if either should change, the Company may recognize a different amount of deferred revenue over the next 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 the future. 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 future periods.

Additional information on the Company's collaborative arrangements is included in Note (8).

*(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 and receivables. The estimated fair values of these financial instruments approximate their carrying values as of December 31, 2009 and 2008, respectively. As of December 31, 2009 and 2008, the Company does not have any derivatives, hedging instruments or other similar financial instruments.

*(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, 2009, 2008 and 2007 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 (loss) income on the accompanying balance sheets.

*(i) Net Income (Loss) per Common Share*

Basic and diluted net loss per common share is computed using the weighted average number of shares of common stock outstanding during the period. In addition, diluted net income per common share is calculated to give effect of stock options, warrants and convertible debt (where the effect is not antidilutive) resulting in lower net income per share. The dilutive effect of outstanding stock options 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 is the same as basic net loss per common share for the year ended December 31, 2007 as the effects of the Company's potential common stock equivalents are antidilutive (see Note 13).

*(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

Table of Contents**IDERA PHARMACEUTICALS, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

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, 2009 and 2008, all assets were located in the United States.

*(k) Stock-Based Compensation*

The Company recognizes all share-based payments to employees 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. The Company included charges of \$3,093,000, \$2,628,000 and \$1,582,000 in its statements of operations for the years ended December 31, 2009, 2008 and 2007, respectively, representing the stock compensation expense attributable to share-based payments made to employees and directors. In spite of the lower number of options granted during 2009, as compared to 2008, employee/director stock compensation expense increased during 2009 primarily due to options granted in December 2008 that were amortized for a full year during 2009 but for less than a month during 2008. Options that became fully amortized in 2008 or early 2009 only partially offset this increase.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model and expensed over the requisite service period on a straight-line basis. The following assumptions apply to the 1,128,000, 1,336,000 and 274,000 options granted to employees and directors during the years ended December 31, 2009, 2008 and 2007:

	<b>2009</b>	<b>2008</b>	<b>2007</b>
Average risk free interest rate	2.5%	2.4%	4.4%
Expected dividend yield			
Expected lives (years)	5.0	4.9	5.9
Expected volatility	66%	66%	70%
Weighted average grant date fair value of options granted during the period (per share)	\$ 3.07	\$ 6.28	\$ 5.81
Weighted average exercise price of options granted during the period (per share)	\$ 5.39	\$ 11.18	\$ 8.86

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, 2009 were granted at exercise prices equal to the fair market value of the common stock on the dates of grant.

The intrinsic value of options exercised amounted to \$81,000, \$2,244,000 and \$551,000 during 2009, 2008 and 2007, respectively. The fair value of options that vested amounted to \$3,461,000, \$2,896,000 and \$1,609,000 during 2009, 2008, and 2007, respectively. As of December 31, 2009, there was \$8,158,000 of unrecognized compensation cost related to unvested stock-based compensation arrangements, which is expected to be recognized over a weighted average period of 2.9 years.

The Company also awarded non-employee, non-director stock options to purchase 10,000, 87,250 and 5,000 shares of common stock during 2009, 2008 and 2007, respectively. These options had Black-Scholes fair values of \$58,000, \$1,055,000 and \$34,000 at the time of grant during 2009, 2008 and 2007, respectively based on the following assumptions:

	<b>2009</b>	<b>2008</b>	<b>2007</b>
Average risk free interest rate	3.7%	3.9%	4.8%
Expected dividend yield			
Expected lives (years)	10.0	10.0	10.0
Expected volatility	88%	94%	98%

F-11

---

**Table of Contents****IDERA PHARMACEUTICALS, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

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. Approximately \$9,000, \$398,000 and \$519,000 was recorded as an expense for these options in 2009, 2008 and 2007, respectively.

There was approximately \$56,000, \$53,000 and \$27,000 in compensation expense related to the Company's 1995 Employee Stock Purchase Plan during 2009, 2008 and 2007, respectively. This expense was computed based on the Black-Scholes option pricing model and the following assumptions:

	2009	2008	2007
Average risk free interest rate	0.2%	2.1%	4.7%
Expected dividend yield			
Expected lives (months)	3.0	3.0	3.0
Expected volatility	68%	70%	72%

During 2007, the Company awarded a restricted stock award of 62,500 shares of its common stock to an employee. The stock's \$441,000 fair market value on the date of the grant is being amortized over the three-year vesting period. \$147,000, \$147,000 and \$73,000 of amortization was expensed during 2009, 2008 and 2007, respectively. 20,833 shares subject to this restricted stock grant vested during each of the years 2009 and 2008. None of the shares subject to this restricted stock grant vested during 2007.

*(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 and 2008, Merck KGaA sponsored approximately \$3.1 million and \$1.4 million, respectively, of the Company's research and development activities. In 2009, 2008 and 2007, Merck & Co. sponsored approximately \$0.8 million, \$1.5 million and \$1.1 million, respectively, of the Company's research and development activities.

*(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, 2009, all of the Company's cash, cash equivalents, and investments 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



Table of Contents**IDERA PHARMACEUTICALS, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

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, 2009 and 2008 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)
<b>December 31, 2009</b>				
Assets				
Money market funds	\$ 25,426	\$ 25,426	\$	\$
Short-term investments	6,270	1,993	4,277	
Long-term investments	8,466	7,214	1,252	
Total Assets	\$ 40,162	\$ 34,633	\$ 5,529	\$
Liabilities	\$	\$	\$	\$
<b>December 31, 2008</b>				
Assets				
Money market funds	\$ 44,842	\$ 44,842	\$	\$
Investments	10,441		10,441	
Total Assets	\$ 55,283	\$ 44,842	\$ 10,441	\$
Liabilities	\$	\$	\$	\$

The Level 1 assets consist of money market funds and U.S. Government bond investments, both of which are actively traded daily. The Level 2 assets consist of federal agency 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 gains or losses are recorded in other comprehensive gains or losses in the equity section of the balance sheet. The Company did not elect to measure any other financial assets or liabilities at fair value.

*(o) Subsequent Events*

The Company evaluates subsequent events occurring between the most recent balance sheet date and the date that the financial statements are available to be issued in order to determine whether the subsequent events are to be recorded in and/or disclosed in the Company's financial statements and footnotes. The financial statements are considered to be available to be issued at the time that they are filed with the Securities and Exchange Commission.

*(p) New Accounting Pronouncements*

On January 1, 2009, the Company adopted Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 808-10 (*Prior authoritative literature: Emerging Issues Task Force (EITF) 07-1, Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*) on a retrospective basis for all collaborative arrangements existing as of January 1, 2009. ASC 808-10

**Table of Contents**

**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

defines collaborative arrangements and establishes reporting requirements for transactions between participants in collaborative arrangements and between participants in the arrangement and third parties. The adoption of ASC 808-10 did not have a material impact on the Company's financial statements.

In June 2009, the FASB issued new guidance concerning the organization of authoritative guidance under Generally Accepted Accounting Principles (GAAP). This new guidance created the FASB Accounting Standards Codification (ASC). The ASC has become the single source of authoritative nongovernmental GAAP. Rules and interpretive releases of the SEC under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. The ASC is effective for interim and annual periods ending after September 15, 2009. On its effective date, the ASC superseded all then-existing non-SEC accounting and reporting standards. All other non-SEC accounting literature not included in the ASC has become nonauthoritative. As the ASC is not intended to change or alter existing GAAP, it did not have any impact on the Company's consolidated financial statements upon adoption.

During the second quarter of 2009, the Company adopted ASC 825-10 (*Prior authoritative literature: FASB Staff Position No. FAS 107-1 and APB 28-1, Interim Disclosures about Fair Value of Financial Instruments*). ASC 825-10 requires disclosures about the fair value of financial instruments in interim as well as in annual financial statements. The adoption of ASC 825-10 did not have a significant impact on the Company's financial position or results of operations.

During the second quarter of 2009, the Company adopted ASC 820-10 (*Prior authoritative literature: FASB Staff Position No. FAS 157-4, Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly*). ASC 820-10 provides additional guidelines for making fair value measurements, provides authoritative guidance in determining whether a market is active or inactive and whether a transaction is distressed. ASC 820-10 requires additional disclosures of the input and valuation techniques used to measure fair value and the defining of the major security types comprising debt and equity securities held based upon the nature and risk of the security. The adoption of ASC 820-10 did not impact the Company's financial position or results of operations.

During the second quarter of 2009, the Company adopted ASC 320-10 (*Prior authoritative literature: FASB Staff Position No. FAS 115-2 and FAS 124-2, Recognition and Presentation of Other-Than-Temporary Impairments*). ASC 320-10 changes existing accounting requirements for other-than-temporary impairment of debt securities. The adoption of ASC 320-10 did not impact the Company's financial position or results of operations.

During the second quarter of 2009, the Company adopted ASC 855-10 (*Prior authoritative literature: FASB Statement of Financial Accounting Standards No. 165, Subsequent Events*). ASC 855-10 is similar to the subsequent events guidance in the current auditing literature except that it clarifies and discloses the period during which companies monitor subsequent events in order to determine what impact, if any, the subsequent events have on the information disclosed in the financial statements and footnotes. The adoption of ASC 855-10 did not impact the Company's financial position or results of operations.

In October 2009, the FASB issued new accounting requirements for accounting for revenue recognition under multiple-element arrangements, which will be effective for fiscal years beginning after June 15, 2010. The Company is currently evaluating the effect of these new requirements on its financial statements.



Table of Contents**IDERA PHARMACEUTICALS, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)****(3) Marketable Securities**

The Company's available-for-sale investments at market value consisted of the following at December 31, 2009 and 2008:

	Cost	December 31, 2009		Estimated Fair Value
		Gross Unrealized (Losses) (In thousands)	Gross Unrealized Gains	
Agency bonds due in one year or less	\$ 4,283	\$ (6)	\$	\$ 4,277
U.S. government bonds due in one year or less	1,994	(1)		1,993
Total short-term investments	6,277	(7)		6,270
Agency bonds due in one year or more	1,256	(4)		1,252
U.S. government bonds due in one year or more	7,222	(8)		7,214
Total long-term investments	8,478	(12)		8,466
Total investments	\$ 14,755	\$ (19)	\$	\$ 14,736

  

	Cost	December 31, 2008		Estimated Fair Value
		Gross Unrealized (Losses) (In thousands)	Gross Unrealized Gains	
Corporate bonds due in one year or less	\$ 10,477	\$ (44)	\$ 8	\$ 10,441
Total investments	\$ 10,447	\$ (44)	\$ 8	\$ 10,441

See Note 2 (g).

**(4) Property and Equipment**

At December 31, 2009 and 2008, net property and equipment at cost consists of the following:

	<b>December 31,</b>	
	<b>2009</b>	<b>2008</b>
	<b>(In thousands)</b>	
Leasehold improvements	\$ 514	\$ 514
Laboratory equipment and other	2,811	2,694
Total property and equipment, at cost	3,325	3,208
Less: Accumulated depreciation	1,938	1,384
Property and equipment,	\$ 1,387	\$ 1,824

As of December 31, 2009 and 2008, laboratory equipment and other included approximately \$79,000 of office equipment financed under capital leases with accumulated depreciation of approximately \$41,000 and \$25,000, respectively.

Depreciation expense, which includes amortization of assets recorded under capital leases, was approximately \$563,000 and \$530,000 and \$364,000 in 2009, 2008 and 2007, respectively.

In 2009, the Company wrote off unused property and equipment that had a gross cost and accumulated depreciation of approximately \$9,000 resulting in no gain or loss. In 2008 and 2007, the Company wrote off unused property and equipment that had a gross cost of approximately \$200,000 and 874,000 respectively. The write-off of

**Table of Contents****IDERA PHARMACEUTICALS, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

property and equipment in 2008 and 2007 resulted in losses of approximately \$2,000 and \$6,000, respectively. The Company also wrote off approximately \$445,000 in fully depreciated leasehold improvements in connection with its relocation to a new facility in 2007.

**(5) Accrued Expenses**

At December 31, 2009 and 2008, accrued expenses consisted of the following:

	<b>December 31,</b>	
	<b>2009</b>	<b>2008</b>
	<b>(In thousands)</b>	
Payroll and related costs	\$ 88	\$ 73
Clinical and nonclinical trial expenses	332	705
Professional and consulting fees	226	230
Other	285	191
	<b>\$ 931</b>	<b>\$ 1,199</b>

**(6) Debt***(a) Note Payable*

In June 2007, the Company executed a promissory note in the aggregate principal amount of \$1,278,000 (the Note) in favor of General Electric Capital Corporation (GE). The Note was fully secured by specific laboratory, manufacturing, office and computer equipment and was subject to the terms of a master security agreement dated April 23, 2007 by and between the Company and GE. The Note bore interest at a fixed rate of 11% per annum, and was payable in 48 consecutive monthly installments of principal and accrued interest, with the first installment having been paid out of the proceeds of the borrowing.

In March 2008, the Company paid approximately \$1,189,000 to GE as payment in full of all obligations outstanding under the Note. The payment represented approximately \$1,121,000 of principal plus accrued interest through the date of payment of approximately \$12,000 and a prepayment premium of approximately \$56,000. Upon payment, the Note was cancelled.

*(b) 4% Convertible Notes Payable*

In 2005, the Company sold approximately \$5,033,000 in aggregate principal amount of 4% convertible subordinated notes due April 30, 2008 (the 4% Notes). In February 2007, the Company automatically converted these 4% Notes into 706,844 shares of the Company's common stock. In accordance with the terms of the 4% Notes and an agreement dated May 20, 2005 among the Company and the holders of the 4% Notes, the Company was entitled to exercise this right of automatic conversion because the volume-weighted average of the closing prices of the Company's common

stock for a period of ten consecutive trading days exceeded \$8.90 per share, which represented 125% of the conversion price of the 4% Notes. As of February 20, 2007, the 4% Notes were no longer considered outstanding and interest ceased to accrue. Holders of the 4% Notes were paid cash in lieu of any fractional shares and \$61,000 in accrued interest through February 19, 2007.

The Company capitalized its financing costs associated with the sale of the 4% Notes and amortized these costs as interest expense through February 19, 2007. The unamortized balance of the deferred financing costs of \$266,000 was reclassified to additional paid-in-capital in connection with the automatic conversion of the 4% Notes.



Table of Contents**IDERA PHARMACEUTICALS, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)****(7) Unrealized Losses**

Investments with unrealized losses are those investments whose cost exceeds market value. Investments with unrealized losses are as follows:

(In thousands)	Investments in Continuous Unrealized Loss Positions for		Total Investments in Unrealized Loss Position
	Less than 12 Months	More than 12 Months	
<b>Short-term investments at December 31, 2009</b>			
Aggregate fair value of investments with unrealized losses (includes accrued interest of \$6)	\$ 6,276	\$	\$ 6,276
Aggregate amount of unrealized losses	\$ 7	\$	\$ 7
<b>Long-term investments at December 31, 2009</b>			
Aggregate fair value of investments with unrealized losses (includes accrued interest of \$36)	\$ 6,297	\$	\$ 6,297
Aggregate amount of unrealized losses	\$ 12	\$	\$ 12
<b>Short-term investments at December 31, 2008</b>			
Aggregate fair value of investments with unrealized losses (includes accrued interest of \$69)	\$ 5,269	\$	\$ 5,269
Aggregate amount of unrealized losses	\$ 44	\$	\$ 44

There were no long-term investments at December 31, 2008.

**(8) Collaboration and License Agreements***(a) Collaboration and License Agreement with Novartis International Pharmaceutical, Ltd.*

In May 2005, the Company entered into a research collaboration and option agreement and a separate license, development, and commercialization agreement with Novartis to discover, develop, and potentially commercialize TLR9 agonists that are identified as potential treatments for asthma and allergies. Under the terms of the agreements,

upon execution of the agreements, Novartis paid the Company a \$4.0 million upfront license fee and Novartis agreed to fund substantially all research activities during the research collaboration phase.

The Company and Novartis initially agreed that the term of the research and collaboration phase would be two years commencing in May 2005. As a result, the Company initially was recognizing the \$4.0 million upfront payment as revenue over the two-year term of the research collaboration. In 2007, Novartis extended the research collaboration by an additional year until May 2008. In connection with this extension, Novartis paid the Company an additional license fee of \$1.0 million. In connection with this amendment, the Company extended the time period over which it was amortizing the upfront payment and the \$1.0 million extension payment. In 2008, the term of the research collaboration was further extended until December 31, 2008. The Company further extended the period over which it was amortizing the upfront payment and the extension payment through the third quarter of 2008 by which time the Phase 1 clinical study of QAX935 had been initiated and the Company's obligations under the agreement ended.

In September 2008, the Company announced that Novartis had initiated a Phase 1 clinical study of QAX935, a novel agonist of TLR9. As a result of the initiation of this Phase 1 clinical study, the Company received a \$1.0 million milestone payment, which was recognized as revenue in 2008.

**Table of Contents**

**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

In November 2009, Novartis notified the Company that it was terminating the research collaboration and option agreement, effective as of February 2010. This termination canceled Novartis' option to implement the license, development, and commercialization agreement. The Company regains all rights to QAX935, which the Company refers to as IMO-2134, without any financial obligations to Novartis and will no longer be subjected to restrictions under the collaboration on its right to develop TLR-targeted compounds, including TLR antagonist and TLR antisense compounds, for respiratory disease. Sponsorship of the trial initiated by Novartis has not been transferred to us.

*(b) Collaboration and License Agreement with Merck & Co., Inc.*

In December 2006, the Company entered into an exclusive license and research collaboration agreement with Merck & Co. 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, the Company granted Merck & Co. worldwide exclusive rights to a number of the Company's TLR7, 8 and 9 agonists for use in combination with Merck & Co.'s therapeutic and prophylactic vaccines under development in the fields of cancer, infectious diseases, and Alzheimer's disease. The Company also agreed with Merck & Co. to engage in a two-year research collaboration to generate novel agonists targeting TLR7 and TLR8 incorporating both Merck & Co. and Idera chemistry for use in vaccines in the defined fields, which may be extended by Merck & Co. for two additional one-year periods. Under the terms of the agreement: Merck & Co. paid the Company a \$20.0 million upfront license fee; Merck & Co. purchased \$10.0 million of the Company's common stock at \$5.50 per share; and Merck & Co. agreed to fund the research and development collaboration. Merck & Co. 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 & Co. develops and commercializes additional vaccines using the Company's agonists, it would be entitled to receive additional milestone payments. In addition, Merck & Co. 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.

The Company is recognizing the \$20.0 million upfront payment as revenue over the two-year initial research term and the additional two-year-period over which the research term has been extended. In November 2008, Merck & Co. extended the research collaboration for an additional one-year period to December 2009. In November 2009, Merck & Co. extended the research collaboration for the fourth and final year to December 2010. The Company has estimated that this is its period of continuing involvement under the research arrangement.

In December 2006, in connection with the execution of the license and collaboration agreement, the Company entered into a stock purchase agreement with Merck & Co. Pursuant to the purchase agreement, the Company issued and sold to Merck & Co. 1,818,182 shares of the Company's common stock for a price of \$5.50 per share resulting in an aggregate gross proceeds of \$10.0 million. Merck & Co. agreed, subject to certain exceptions, that prior to December 8, 2007, it would not sell any of the shares of the Company's common stock acquired by it and that, for the duration of the research and collaboration term, its ability to sell such shares will be subject to specified volume limitations.

In May 2008, under the Company's collaboration with Merck & Co., a preclinical milestone was achieved with one of its novel TLR9 agonists used as an adjuvant in cancer vaccines. As a result, the Company received a \$1.0 million milestone payment from Merck & Co., which was recognized as revenue in 2008.

F-18

---

**Table of Contents**

**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

*(c) 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 became effective February 4, 2008. Under the terms of the agreement, Idera 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 Idera continued to conduct the trials on behalf of Merck KGaA; Merck KGaA agreed to pay up to EUR 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 our TLR9 agonists that are marketed. In February 2009, the agreement was amended so that the Company 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 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. As of March 2010, Merck KGaA is now the sponsor of all clinical trials of IMO-2055 for the treatment of cancer and has assumed responsibility for all further clinical development of IMO-2055 in the treatment of cancer.

The Company is recognizing the \$40.0 million upfront payment as revenue over the twenty eight-month research term. The Company has estimated that this is its period of continuing involvement under the research arrangement. In 2009, the Company earned milestone revenue of \$8.3 million under its collaboration with Merck KGaA relating to the dosing in January 2009 of the first patient in the clinical trial of IMO-2055 in patients with colorectal cancer and to the initiation in December 2009 of a Phase 2 clinical trial of IMO-2055 in patients with recurrent or metastatic squamous cell carcinoma of the head and neck. See Note (17).

*(d) 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 our 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's 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 our 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 us of the patents and patent applications.

**Table of Contents**

**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

In addition, the Company has entered into three license agreements involving the license of our 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 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 six 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.

**(9) 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, 2009, the Company has repurchased or received documentation of the transfer of 399,950 Put Shares and 99,261 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 700,474 Put Shares have terminated.

F-20

---



**Table of Contents****IDERA PHARMACEUTICALS, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)***(b) Warrants*

The Company has the following warrants outstanding and exercisable for the purchase of common stock at December 31, 2009:

<b>Expiration Date</b>	<b>Shares</b>	<b>Weighted Average Exercise Price Per Share</b>
September 24, 2011	2,466,263	\$ 5.42

*(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 three 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. 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, 2009, options to purchase a total of 1,786,206 shares of common stock remained outstanding under the 2008 Stock Incentive Plan. As of December 31, 2009, 1,910,357 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, 2009, options to purchase a total of 2,453,779 shares of common stock were outstanding under these plans.

The Company's share-based compensation plans have been approved by the Company's stockholders. In 2001, the Company also granted options to purchase shares of Common Stock pursuant to agreements outside of these plans that were not approved by stockholders.

Table of Contents**IDERA PHARMACEUTICALS, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

The following table summarizes information related to the outstanding and exercisable options during 2009 (in thousands, except per share amounts and years):

	<b>Stock Options</b>	<b>Weighted-Average Exercise Price</b>	<b>Weighted-Average Remaining Contractual Life (in years)</b>	<b>Aggregate Intrinsic Value</b>
Outstanding at December 31 2008	3,546	\$ 7.92		
Granted	1,138	5.40		
Exercised	(42)	4.11		
Forfeited	(52)	7.98		
Expired	(25)	6.45		
Outstanding at December 31, 2009	4,565	\$ 7.34	6.91	\$ 744
Exercisable at December 31, 2009	2,545	\$ 7.09	5.09	\$ 720
Total exercisable or expected to vest	4,502	\$ 7.34	6.88	\$ 743

*(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.

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 2009, 2008, and 2007, the Company issued 28,074, 11,926 and 10,364 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. As of December 31, 2009 and 2008, there were 655 shares of Series A convertible preferred stock outstanding.

As discussed in Note (15), the Company has designated Series C junior participating preferred stock in connection with its shareholder rights plan. During 2002, the Company designated 100,000 shares of Series C junior

**Table of Contents****IDERA PHARMACEUTICALS, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

participating preferred stock. The Company designated an additional 50,000 shares of Series C junior participating preferred stock in each of the years 2003 and 2005. There were no shares of Series C junior participating preferred stock issued or outstanding at either December 31, 2009 or 2008.

*(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.

**(10) Commitments and Contingencies***(a) Lease Commitments*

In June 2007, the Company relocated its operations to a newly leased facility. The Company entered into a lease arrangement on October 31, 2006 and the term of the lease commenced on June 1, 2007 and will terminate on May 31, 2014, with one five-year renewal option exercisable by the Company. During 2009, 2008 and 2007, rent expense, including real estate taxes and net of sublease income that ended in January 2007, was \$1,467,000, \$1,576,000 and \$1,221,000, respectively. As part of the lease, the Company was required to restrict approximately \$619,000 of cash for a security deposit of which \$516,000 remains restricted as of December 31, 2009. The lease is classified as an operating lease. Total payments over the seven-year term of the lease are approximately \$9.0 million. Future minimum commitments as of December 31, 2009 under the Company's lease agreement are approximately:

<b>December 31,</b>	<b>Operating Lease (In thousands)</b>
2010	\$ 1,346
2011	1,391
2012	1,436
2013	1,483
2014	626
	<b>\$ 6,282</b>

*(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 2012, with its president, chief executive officer and chief scientific officer. As of December 31, 2009, future minimum commitments under this agreement

F-23

---

Table of Contents**IDERA PHARMACEUTICALS, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

are approximately \$530,000, \$530,000 and \$425,000 for the years ended December 31, 2010, 2011, and 2012, respectively.

*(d) Related-Party Transactions*

The Company paid directors consulting fees of approximately \$16,000 and \$101,000 in 2009 and 2008, respectively. The Company issued common stock in lieu of Director board and committee fees of approximately \$7,000, \$7,000 and \$20,000 during 2009, 2008 and 2007, respectively. There were no consulting fees paid to directors during 2007.

**(11) Income Taxes**

Subject to the limitations described below, at December 31, 2009, the Company had cumulative net operating loss carryforwards (NOLs) of approximately \$249.3 million and \$30.9 million available to reduce federal and state taxable income which expire through 2029 and 2014, respectively. In addition, the Company had cumulative federal and state tax credit carryforwards of \$5.4 million and \$4.6 million, respectively, available to reduce federal and state income taxes which expire through 2029 and 2024, respectively. The NOLs include approximately \$1.9 million of deductions related to the exercise of stock options subsequent to the adoption of ASC 718. 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 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%. The Company has completed several financings since the effective date of the Tax Reform Act of 1986, which as of December 31, 2009, 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 estimated that between 30% and 45% of the \$249.3 million in federal NOLs could be utilized to offset federal taxable income and approximately 66% of the \$5.4 million of federal tax credit carryforwards could be used to offset federal income taxes. 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, 2009 and 2008, the components of the deferred tax assets are approximately as follows:

	<b>2009</b>	<b>2008</b>
	<b>(In thousands)</b>	
Operating loss carryforwards	\$ 85,655	\$ 95,680
Tax credit carryforwards	8,487	8,361
Other	7,164	5,624
	101,306	109,665
Valuation allowance	(101,306)	(109,665)
	\$	\$

The Company has provided a valuation allowance for its deferred tax asset due to the uncertainty surrounding the ability to realize this asset. The valuation allowance in the current year has decreased by approximately \$8.4 million which is attributable to a decrease in deferred tax assets associated with the expiration and utilization of NOLs.

For the years ended December 31, 2009, 2008 and 2007, the primary reason for the difference between the income tax provision (benefit) recorded by the Company and the amount of the income tax benefit at statutory income tax rates was the change in the valuation allowance.

F-24

---

**Table of Contents**

**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

The Company adopted the Accounting Standards Codification 740-10 *Accounting for Uncertainty in Income Taxes, an interpretation of ASC 740* ( ASC 740-10 ), effective January 1, 2007. 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 adoption of ASC 740-10 did not have any effect on the Company's financial position or results of operations.

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, 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 2006, except to the extent that it utilizes NOLs or tax credit carryforwards that originated before 2006. 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.

The Company recorded approximately \$150,000 in Alternative Minimum Tax (AMT) as income tax expense during the nine months ended September 30, 2009. The \$150,000 was reversed during the three months ended December 31, 2009 as a result of the enactment of the Worker, Homeownership, and Business Assistance Act of 2009 (the Act ) in November, 2009. The Act contains a number of tax law changes, including a provision that permits companies to carry back certain NOLs up to five years. Under existing tax law prior to the Act, most companies can carry back an NOL a maximum of two years to offset taxable income. The Act generally permits companies to elect to carry back an applicable NOL up to five years. The Act also suspends the 90% limit on the utilization of AMT losses, effectively permitting AMT taxpayers to elect to carry back their entire applicable NOL and then carry that NOL forward without the 90% limitation. In addition to the 2009 AMT reversal, the Company recognized tax benefits for the carryback of NOLs to recover \$50,000 in 2006 AMT during the three months ended December 31, 2009.

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. In the three months ended March 31, 2008, the Company made an estimated quarterly tax payment and recorded income tax expense of \$50,000 as a result of the payment from Merck KGaA generating income that the Company believed would be subject to AMT. The Company subsequently reversed the \$50,000 recorded as income tax expense as the Company no longer expected to have income subject to AMT. The Company did not have income subject to AMT in 2007.

**(12) 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 \$130,000, \$78,000 and \$118,000 of 401(k) benefits were charged to operating expenses during 2009, 2008 and 2007, respectively.

F-25

---

**Table of Contents****IDERA PHARMACEUTICALS, INC.****NOTES TO FINANCIAL STATEMENTS (Continued)****(13) Income per Share**

The following table sets forth the computation of basic and diluted income per share for the years ended December 31, 2009 and 2008:

<b>(In thousands, except per share amounts)</b>	<b>December 31,</b>	
	<b>2009</b>	<b>2008</b>
Numerator for basic and dilutive net income per share:		
Net income	\$ 7,546	\$ 1,509
Denominator for basic income per share:		
Weighted average common shares outstanding	23,420	22,655
Effects of dilutive securities:		
Effect of restricted stock grant	31	52
Effect of dilutive common stock options and warrants	628	2,624
Denominator for diluted income per share	24,079	25,331
Basic income per share	\$ 0.32	\$ 0.07
Diluted income per share	\$ 0.31	\$ 0.06

For the years ended December 31, 2009 and 2008, 2,211,000 and 1,117,000 shares, respectively, were not included in the computation of diluted net income per share as the effects of certain stock options, warrants and convertible preferred stock are antidilutive. Net income applicable to common stockholders is the same as net income for 2009 and 2008.

For the year ended December 31, 2007, basic and diluted net loss per common share is computed using the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share of common stock is the same as basic net loss per share of common stock for 2007, as the effects of the Company's potential common stock equivalents are antidilutive. Total antidilutive securities were approximately 7,210,000 at December 31, 2007 and consist of stock options, warrants and convertible preferred stock. Net loss applicable to common stockholders is the same as net loss for year ended December 31, 2007.

**(14) Supplemental Disclosure of Cash Flow Information**

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

**Years Ended December 31,**

	<b>2009</b>	<b>2008</b>	<b>2007</b>
	<b>(In thousands)</b>		
Supplemental disclosure of cash flow information:			
Cash paid for interest	\$ 3	\$ 92	\$ 149
Cash paid for income taxes	\$ 220	\$ 50	\$ 45
Supplemental disclosure of non cash financing and investing activities:			
Conversion of 4% Convertible Subordinated Notes into Common Stock	\$	\$	\$ 5,033
Issuance of stock options and stock for services	\$ 17	\$ 22	\$ 44
Equipment acquired under capital lease	\$	\$	\$ 78

F-26

---

**Table of Contents**

**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**(15) Shareholder Rights Plan**

The Company adopted a shareholder rights plan in December 2001. Under the rights plan, one right was distributed as of the close of business on January 7, 2002 on each then outstanding share of the Company's common stock. As a result of the June 2006 reverse stock split, the number of rights associated with each share of common stock was automatically proportionately adjusted so that (i) eight rights were then associated with each outstanding share of common stock and (ii) so long as the rights are attached to the common stock, eight rights (subject to further adjustment pursuant to the provisions of the rights plan) shall be deemed to be delivered for each share of common stock issued or transferred by the Company in the future. The rights will automatically trade with the underlying common stock and ordinarily will not be exercisable. The rights will only become exercisable, subject to certain exclusions, if a person acquires beneficial ownership of, or commences a tender offer for, fifteen percent or more of the Company's common stock, unless, in either case, the transaction was approved by the Company's board of directors.

If the rights become exercisable, the type and amount of securities receivable upon exercise of the rights would depend on the circumstances at the time of exercise. Initially, each right would entitle the holder to purchase one one-thousandth of a share of the Company's Series C junior participating preferred stock for an exercise price of \$13.00. If a person (other than an exempt person) acquires fifteen percent or more of the Company's common stock in a transaction that was not approved by the Company's board of directors, then each right, other than those owned by the acquiring person, would instead entitle the holder to purchase \$26.00 worth of the Company's common stock for the \$13.00 exercise price. If the Company is involved in a merger or other transaction with another company in which the Company is not the surviving corporation, or transfers more than 50% of its assets to another company, in a transaction that was not approved by the Company's board of directors, then each right, other than those owned by the acquiring person, would instead entitle the holder to purchase \$26.00 worth of the acquiring company's common stock for the \$13.00 exercise price.

The Company's board of directors may redeem the rights for \$0.001 per right at any time until ten business days after a person acquires fifteen percent or more of the Company's outstanding common stock. Unless the rights are redeemed or exchanged earlier, they will expire on December 10, 2011.

**(16) Warrant Redemptions**

In January 2008, the Company sent notice to holders of the Company's warrants to purchase common stock that were issued in August 2004 with an expiration date of August 27, 2009 (the August 2004 Warrants) that under the terms of the warrant agreement, it intended to redeem on March 31, 2008 any August 2004 Warrants not exercised as of that date for a redemption price of \$0.08 per share of common stock underlying the August 2004 Warrants. The Company was entitled to exercise this redemption right because the closing price of the Company's common stock for twenty consecutive trading days ending December 20, 2007 was greater than \$10.72 or 200% of the exercise price of the warrant. The August 2004 Warrants were exercisable by cash payment only and had an exercise price of \$5.36 per share of common stock. Following such notice and through March 31, 2008, the Company received approximately \$1,472,000 in proceeds from the exercise of August 2004 Warrants to purchase 274,650 shares of common stock. As of March 31, 2008, all August 2004 Warrants had been exercised.

In June 2008, the Company sent notice to Pillar Investment Limited, the holder of a warrant to purchase 70,684 shares of the Company's common stock that was issued in May 2005 with an expiration date of May 24, 2010 (the May 2005 Warrant) that under the terms of the warrant agreement it intended to redeem on September 12, 2008 the May 2005 Warrant if not exercised as of that date for a redemption price of \$0.08 per share of common stock underlying the May 2005 Warrant. The Company was entitled to exercise this redemption right because the closing price of the Company's common stock for twenty consecutive trading days ending June 3, 2008 was greater than \$14.24 or 200% of the exercise price of the warrant. The May 2005 Warrant was exercisable by cash payment only and had an exercise price of \$7.12 per share of common stock. Following such notice, the Company received approximately \$503,000 in proceeds from the exercise of the May 2005 warrant to purchase

**Table of Contents**

**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

70,684 shares of common stock. The May 2005 warrant was exercised in September 2008. Pillar Investment Limited is controlled by a director of the Company.

**(17) Subsequent Events**

In February 2010, the Company received payment of \$4.1 million related to achievement of a milestone under its agreement with Merck KGaA in connection with the initiation of a Phase 2 clinical trial of IMO-2055 in patients with recurrent or metastatic squamous cell carcinoma of the head and neck. This milestone was earned in 2009 and was included in revenue for the year ended December 31, 2009. The \$4.1 million payment received in 2010 was approximately \$0.2 million less than the \$4.3 million receivable recorded at December 31, 2009 due to foreign currency exchange rates in effect at the time payment was received. This \$0.2 million will be reported as a foreign currency loss in the first quarter of 2010.

F-28

---

**Table of Contents****Exhibit Index**

Exhibit Number	Description	Filed Herewith	Incorporated by Reference to		
			Form	Filing 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	Rights Agreement dated December 10, 2001 by and between Idera Pharmaceuticals, Inc. and Mellon Investor Services LLC, as rights agent.		S-2	October 10, 2003	333-109630
4.3	Amendment No. 1 to Rights Agreement dated as of August 27, 2003 between Idera Pharmaceuticals, Inc. and Mellon Investor Services LLC, as rights agent.		8-K	August 29, 2003	000-27352
4.4	Amendment No. 2 to Rights Agreement dated as of March 24, 2006 between Idera Pharmaceuticals, Inc. and Mellon Investor Services LLC, as rights agent.		8-K	March 29, 2006	001-31918
4.5	Amendment No. 3 to Rights Agreement dated January 16, 2007 between Idera Pharmaceuticals, Inc. and Mellon Investor Services, LLC, as rights agent.		8-K	January 17, 2007	001-31918
10.1	2008 Stock Incentive Plan.		8-K	June 10, 2008	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 Stock Option Plan.		S-1	November 6, 1995	33-99024
10.5	1995 Director Stock Option Plan.		8-K	June 10, 2008	001-31918
10.6	1995 Employee Stock Purchase Plan, as amended.		8-K	June 10, 2008	001-31918
10.7	Non-Employee Director Nonstatutory Stock Option Agreement Granted under 1997 Stock Incentive Plan.		10-K	March 25, 2005	001-31918
10.8	Form of Incentive Stock Option Agreement Granted Under the 2005 Stock Incentive Plan.		8-K	June 21, 2005	001-31918
10.9	Form of Nonstatutory Stock Option Agreement Granted Under the 2005 Stock Incentive Plan.		8-K	June 21, 2005	001-31918

Edgar Filing: IDERA PHARMACEUTICALS, INC. - Form 10-K

10.10	Form of Restricted Stock Agreement Under the 2005 Stock Incentive Plan.	10-Q	August 1, 2007	001-31918
10.11	Form of Incentive 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 Granted Under the 2008 Stock Incentive Plan.	8-K	June 10, 2008	001-31918

---



**Table of Contents**

Exhibit Number	Description	Filed Herewith	Incorporated by Reference to		
			Form	Filing Date	SEC File No.
10.13	Form of Nonstatutory Stock Option Agreement (Non-Employee Directors) Granted Under the 2008 Stock Incentive Plan.		8-K	June 10, 2008	001-31918
10.14	Form of Restricted Stock Agreement Under the 2008 Stock Incentive Plan.		8-K	June 10, 2008	001-31918
10.15	Director Compensation Program Effective February 1, 2010.	X			
10.16	Employment Agreement dated October 19, 2005 between Idera Pharmaceuticals, Inc. and Dr. Sudhir Agrawal.		10-Q	November 9, 2005	001-31918
10.17	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
10.18	Employment Offer Letter dated November 8, 2007 by and between Idera Pharmaceuticals, Inc. and Louis J. Arcudi, III.		10-K/A	December 24, 2008	001-31918
10.19	Amendment dated December 17, 2008 to Employment Offer Letter by and between Idera Pharmaceuticals, Inc. and Louis J. Arcudi, III, Dated November 8, 2007.		8-K	December 18, 2008	001-31918
10.20	Offer letter by and between Idera Pharmaceuticals, Inc. and Dr. Alice Bexon, dated November 27, 2006, as amended.		10-Q	November 5, 2009	001-31918
10.21	Executive Stock Option Agreement for 1,260,000 Options effective as of July 25, 2001 between Idera Pharmaceuticals, Inc. and Dr. Sudhir Agrawal.		10-Q	October 24, 2002	000-27352
10.22	Executive Stock Option Agreement for 550,000 Options effective as of July 25, 2001 between Idera Pharmaceuticals, Inc. and Dr. Sudhir Agrawal.		10-Q	October 24, 2002	000-27352
10.23	Executive Stock Option Agreement for 500,000 Options effective as of July 25, 2001 between Idera Pharmaceuticals, Inc. and Dr. Sudhir Agrawal.		10-Q	October 24, 2002	000-27352
10.24	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

Edgar Filing: IDERA PHARMACEUTICALS, INC. - Form 10-K

10.25	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
10.26	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

---

**Table of Contents**

Exhibit Number	Description	Filed Herewith	Incorporated by Reference to		
			Form	Filing Date	SEC File No.
10.27	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
10.28	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
10.29	Exclusive License and Research Collaboration Agreement by and between Merck & Co., Inc. and Idera Pharmaceuticals, Inc., dated December 8, 2006.		8-K	March 6, 2007	001-31918
10.30	License Agreement by and between Merck KGaA and Idera Pharmaceuticals, Inc., dated December 18, 2007.		10-K	March 11, 2008	001-31918
10.31	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
10.32	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
10.33	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
10.34	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
10.35	Form of Warrant issued to Investors in Idera Pharmaceuticals, Inc. s March 24, 2006 Private Financing.		8-K	March 29, 2006	001-31918
10.36	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
10.37	Amendment No. 1 to the Registration Rights Agreement dated March 24, 2006, by and among Idera Pharmaceuticals, Inc.		10-Q	August 14, 2006	001-31918

	and Biotech Shares Ltd.			
10.38	Warrant issued to Biotech Shares Ltd. on March 24, 2006.	8-K	March 29, 2006	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		

---

**Table of Contents**

<b>Exhibit Number</b>	<b>Description</b>	<b>Filed Herewith</b>	<b>Incorporated by Reference to</b>		
			<b>Form</b>	<b>Filing Date</b>	<b>SEC File No.</b>
31.2	Certification of Chief Financial Officer 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			

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