

---

**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, 2008  
OR  
 **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission File Number: 001-31918

**IDERA PHARMACEUTICALS, INC.**

(Exact name of Registrant as specified in its certificate of incorporation)

**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:

**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

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer       Accelerated filer       Non-accelerated filer       Smaller reporting company   
(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 \$321,536,000 based on the last sale price of the registrant's common stock as reported on the NASDAQ Global Market on June 30, 2008. As of February 26, 2009, the registrant had 23,422,525 shares of common stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Registrant's Proxy Statement with respect to the Annual Meeting of Stockholders to be held on June 16, 2009 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

	<u>Page</u>	
<b><u>PART I.</u></b>		
<a href="#"><u>Item 1.</u></a>	<a href="#"><u>Business</u></a>	1
<a href="#"><u>Item 1A.</u></a>	<a href="#"><u>Risk Factors</u></a>	18
<a href="#"><u>Item 1B.</u></a>	<a href="#"><u>Unresolved Staff Comments</u></a>	32
<a href="#"><u>Item 2.</u></a>	<a href="#"><u>Properties</u></a>	33
<a href="#"><u>Item 3.</u></a>	<a href="#"><u>Legal Proceedings</u></a>	33
<a href="#"><u>Item 4.</u></a>	<a href="#"><u>Submission of Matters to a Vote of Security Holders</u></a>	33
	<a href="#"><u>Executive Officers of Idera Pharmaceuticals</u></a>	33
<b><u>PART II.</u></b>		
<a href="#"><u>Item 5.</u></a>	<a href="#"><u>Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u></a>	35
<a href="#"><u>Item 6.</u></a>	<a href="#"><u>Selected Financial Data</u></a>	36
<a href="#"><u>Item 7.</u></a>	<a href="#"><u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u></a>	36
<a href="#"><u>Item 7A.</u></a>	<a href="#"><u>Quantitative and Qualitative Disclosures About Market Risk</u></a>	49
<a href="#"><u>Item 8.</u></a>	<a href="#"><u>Financial Statements and Supplementary Data</u></a>	49
<a href="#"><u>Item 9.</u></a>	<a href="#"><u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u></a>	51
<a href="#"><u>Item 9A.</u></a>	<a href="#"><u>Controls and Procedures</u></a>	51
<a href="#"><u>Item 9B.</u></a>	<a href="#"><u>Other Information</u></a>	53
<b><u>PART III.</u></b>		
<a href="#"><u>Item 10.</u></a>	<a href="#"><u>Directors, Executive Officers and Corporate Governance</u></a>	53
<a href="#"><u>Item 11.</u></a>	<a href="#"><u>Executive Compensation</u></a>	53
<a href="#"><u>Item 12.</u></a>	<a href="#"><u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u></a>	53
<a href="#"><u>Item 13.</u></a>	<a href="#"><u>Certain Relationships and Related Transactions and Director Independence</u></a>	53
<a href="#"><u>Item 14.</u></a>	<a href="#"><u>Principal Accountant Fees and Services</u></a>	53
<b><u>PART IV.</u></b>		
<a href="#"><u>Item 15.</u></a>	<a href="#"><u>Exhibits and Financial Statement Schedules</u></a>	54
	<a href="#"><u>EX-10.38 AMENDMENT TO THE CONSULTING SERVICES AGREEMENT</u></a>	
	<a href="#"><u>EX-10.55 AMENDMENT TO THE LICENSE AGREEMENT</u></a>	
	<a href="#"><u>EX-23.1 CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM</u></a>	
	<a href="#"><u>EX-31.1 CERTIFICATION OF CHIEF EXECUTIVE OFFICER</u></a>	
	<a href="#"><u>EX-31.2 CERTIFICATION OF CHIEF FINANCIAL OFFICER</u></a>	
	<a href="#"><u>EX-32.1 CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350</u></a>	
	<a href="#"><u>EX-32.2 CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350</u></a>	

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.

## FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical fact, included or incorporated in this report regarding our strategy, future operations, collaborations, intellectual property, financial position, future revenues, projected costs, prospects, plans, and objectives of management are forward-looking statements. The words “believes,” “anticipates,” “estimates,” “plans,” “expects,” “intends,” “may,” “could,” “should,” “potential,” “likely,” “projects,” “continue,” “will,” and “would” and similar expressions 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 II, 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.

## 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 have not been approved for any commercial use. TLRs are specific receptors present in immune system cells that recognize the DNA or RNA of pathogens such as 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, and cancer. IMO-2125, a TLR9 agonist, is our lead drug candidate for infectious diseases. We are conducting a Phase 1 clinical trial of IMO-2125 in patients with chronic hepatitis C virus, or HCV, infection who have not responded to current standard of care therapy. The trial is designed to assess the safety of IMO-2125. In addition, the trial is designed to evaluate the effects of IMO-2125 on HCV RNA levels and on parameters of immune system activation. We also plan to conduct a clinical trial of IMO-2125 to assess the safety of IMO-2125 in combination with ribavirin in treatment-naïve patients with chronic HCV infection. This clinical trial also will evaluate the effects of IMO-2125 and ribavirin combination treatment on HCV RNA levels and on parameters of immune system activation.

As part of our infectious disease program, we are also evaluating RNA-based compounds that act as agonists of TLR7 and/or TLR8. We refer to our TLR7 and TLR8 agonists as stabilized immune modulatory RNA, or SIMRA, compounds. We are evaluating the mechanism of action of our SIMRA compounds in preclinical studies in human cell-based assays and *in vivo* in non-human primates.

In our autoimmune and inflammatory disease program, we have identified DNA-based compounds that act as antagonists of TLR7 and TLR9. We have evaluated these compounds in mouse models of lupus, rheumatoid arthritis, multiple sclerosis, psoriasis, colitis, and pulmonary inflammation. We have selected IMO-3100 as a lead TLR antagonist drug candidate, and are currently conducting preclinical development studies in anticipation of submitting an Investigational New Drug, or IND, application to the United States Food and Drug Administration, or FDA, by the end of 2009. We have formed an Autoimmune Disease Scientific Advisory Board to assist us in the clinical development strategy for IMO-3100 and other antagonist candidates in autoimmune and inflammatory diseases.

Our cancer treatment research program is focused on potential applications of our TLR7 and/or TLR8 agonists. We are studying our TLR7 and TLR8 agonists in preclinical models of cancer and have observed antitumor activity as monotherapy and in combination with selected targeted agents.

We are also collaborating with three pharmaceutical companies to advance our TLR-targeted compounds in additional disease areas. We are collaborating with Merck KGaA for cancer treatment excluding cancer vaccines, with Merck & Co., Inc., or Merck & Co., for vaccine adjuvants, and with Novartis International Pharmaceutical, Ltd., or Novartis, for treatment of asthma and allergies. Merck KGaA and Merck & Co. are not related.

In December 2007, we entered into a worldwide licensing and collaboration agreement with Merck KGaA for the research, development and commercialization of our TLR9 agonists for the treatment of cancer, excluding

## [Table of Contents](#)

cancer vaccines. Under the agreement, we exclusively licensed our clinical stage drug candidates IMO-2055, a TLR9 agonist, and IMO-2125, as well as other TLR9 agonists, for the treatment of cancer, excluding cancer vaccines. We continue to support Merck KGaA in its clinical development plan. At present, we are conducting on behalf of Merck KGaA a clinical trial of IMO-2055 in combination with Erbitux® and Camptosar® in patients with colorectal cancer, and a clinical trial of IMO-2055 in combination with Avastin® and Tarceva® in patients with non-small cell lung cancer. In February 2009, we achieved a milestone under our agreement with Merck KGaA upon the dosing of the first patient in the Erbitux/Camptosar clinical trial. Under the terms of the agreement, we are entitled to receive a payment of €3.0 million (approximately \$3.8 million) from Merck KGaA in 2009.

In December 2006, we entered into an exclusive license and research collaboration agreement with Merck & Co. to research, develop and commercialize therapeutic and prophylactic vaccine products containing our TLR7, 8 or 9 agonists in the fields of cancer, infectious diseases and Alzheimer's disease. Under the agreement, we are engaged in a research collaboration to generate novel agonists targeting TLR7 and TLR8, which may incorporate both Merck & Co. and Idera chemistry, for use in Merck & Co.'s vaccines for cancer, infectious diseases and Alzheimer's disease. 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. In November 2008, Merck & Co. extended the research collaboration, which was originally for two years, for an additional year to December 2009.

In May 2005, we entered into a research collaboration and option agreement and a license, development, and commercialization agreement with Novartis to discover, develop, and potentially commercialize TLR9 agonists as potential treatments for asthma and allergies. In September 2008, we achieved a milestone under our Novartis collaboration, related to the initiation of a Phase 1 clinical trial by Novartis of QAX935, a novel agonist of TLR9.

### **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 our collaborations with Merck KGaA for cancer treatment excluding cancer vaccines, Merck & Co. for vaccine adjuvants, and Novartis for treatment of asthma and allergies provide the necessary resources and expertise to advance these programs. These collaborations have also brought us up-front payments and milestone payments that have helped to finance our internal research and development programs. These collaborations could also result in us receiving additional payments if agreed upon milestones are achieved. We may also receive royalties if any commercial products result from our collaborations.

As our clinical evaluation of IMO-2125 advances in chronic HCV infection, our development of IMO-3100 continues in anticipation of an IND submission, and our preclinical programs move forward in infectious diseases, autoimmune and inflammatory diseases, and cancer, we may continue to seek additional collaborations. 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 plan to stay at the forefront of TLR-based research and discovery by applying our chemistry-based approach to create and develop 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 pathogenic invasion or to the presence of 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 is presented with a pathogen, cells of the innate immune system are activated, 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 a pathogenic 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. This process is initiated through signals produced by the innate immune system. Upon recognition of a foreign 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.

### **TLR-based Drug Discovery Technology**

The human immune system is activated by recognition of pathogen-associated molecular patterns, or PAMPs. TLRs comprise a family of receptors that are known to recognize PAMPs. The different members of the TLR family of receptors are expressed in various immune system cells and recognize different PAMPs. Of the TLR receptors, TLR9 is a receptor that specifically recognizes certain DNA patterns that occur in 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*

Our most advanced programs are based on drug candidates that are agonists of TLR9. These candidates mimic bacterial DNA and induce immune responses through TLR9 that may be applicable to the treatment of infectious diseases, cancer, and asthma and allergies, and for use as vaccine adjuvants. We have created our TLR9 agonist candidates to activate specific cells of the immune system to 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 determined that the immunological activity of our TLR9 agonists can be changed by modifying the structure. Our ability to change immunological activity by modifying the chemical structure allows us to create a growing portfolio of TLR9 agonist 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. These RNA-based 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 cancer and have observed antitumor activity as monotherapy and in combination with selected targeted agents.

#### *TLR7 and TLR9 Antagonists*

We are creating novel classes of drug candidates that are designed to be antagonists of TLR7 and TLR9. Recent preclinical studies from independent researchers have suggested TLR7 and TLR9 may play a role in certain autoimmune and inflammatory diseases. In cell-based experiments and animal models, our antagonists have blocked immune stimulation in the presence of specific agonists of TLR9 and specific agonists of TLR7. 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, and pulmonary inflammation. In these models, treatment with our antagonist drug candidates was associated with improvement in a number of disease parameters.

#### **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 for our programs.

#### ***INTERNAL RESEARCH AND DEVELOPMENT PROGRAMS***

<b>Disease Area</b>		
<b>Infectious Diseases</b>		
Chronic Hepatitis C	IMO-2125 (TLR9 agonist)	Phase 1 Clinical Trial
Viral Diseases	TLR7, 8 and 9 agonists	Research
<b>Autoimmune and Inflammatory Diseases</b>		
Lupus, Rheumatoid Arthritis, Multiple Sclerosis, Psoriasis, Colitis	IMO-3100 (dual TLR7/TLR9 antagonist)	Preclinical Development
<b>Oncology</b>		
Solid Tumor Cancers	TLR7, TLR8 agonists	Research

#### ***COLLABORATIVE ALLIANCES***

<b>Disease Area</b>		
<b>Oncology: TLR9 agonists in collaboration with Merck KGaA</b>		
Renal Cell Carcinoma	IMO-2055	Phase 2 Stage A Clinical Trial
Non-small Cell Lung Cancer	IMO-2055 in combination with Tarceva® and Avastin®	Phase 1b Clinical Trial
Colorectal Cancer	IMO-2055 in combination with Erbitux® and Camptosar®	Phase 1b Clinical Trial
<b>Vaccine Adjuvants: TLR7, 8, 9 agonists in collaboration with Merck &amp; Co.</b>		
Cancer	TLR7, 8 and 9 agonists	Research
Infectious Disease	TLR7, 8 and 9 agonists	Research
Alzheimer's Disease	TLR7, 8 and 9 agonists	Research
<b>Respiratory Diseases: TLR9 agonists in collaboration with Novartis</b>		
Asthma, Allergies	QAX935 (IMO-2134)	Phase 1 Clinical Trial

*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 that have potential therapeutic applicability in infectious diseases, including those caused by viruses.

Our most advanced application of TLR-targeted drug candidates in infectious diseases involves DNA-based compounds that mimic bacterial DNA and are recognized as agonists of TLR9. Certain TLR9 agonists induce high levels of interferon-alpha in preclinical models. Recombinant interferon products currently are components of the standard of care for viral infectious diseases such as chronic HCV infection.

*Hepatitis C — IMO-2125.* Currently, the standard of care treatment for chronic HCV infection is based on therapies that include a single recombinant interferon protein. We and others have shown in preclinical studies that TLR9 agonists induce many proteins, including natural interferon proteins and other proteins with antiviral activity. The induction of natural interferon and other antiviral proteins through TLR9 leads us to believe that TLR9 agonists may provide advantages over recombinant interferon for the treatment of chronic HCV infection because the induced proteins may act in concert to produce a broader or stronger antiviral effect.

We have selected IMO-2125, a synthetic DNA-based TLR9 agonist, as our lead candidate for the treatment of infectious diseases. In preclinical models, including cultures of human immune cells and in nonhuman primates, IMO-2125 was shown to induce 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 IND for IMO-2125 to the FDA, and in September 2007, we initiated a Phase 1 clinical trial of IMO-2125 in patients with chronic HCV infection who have not responded to the current standard of care therapy. We are currently recruiting patients and plan to enroll up to 40 patients in four cohorts at escalating IMO-2125 dose levels, with four weeks of treatment. Of the ten patients per cohort, eight will be randomized to receive IMO-2125 treatment and two will be randomized to receive placebo treatment. The trial is designed to assess the safety of IMO-2125 at each dose level. In addition, the trial is designed to evaluate the effects of IMO-2125 on HCV RNA levels and on parameters of immune system activation.

In this trial, we are enrolling the first five patients per cohort sequentially and allowing each patient to complete at least two weekly injections prior to enrollment of the next patient. Following a safety review of these first five patients in each cohort, the remaining patients of the cohort are enrolled. Due to this enrollment procedure, completion of each cohort has taken longer than anticipated. Currently, we are recruiting patients into the third cohort of the trial. We currently expect interim results from this trial will be available late in 2009.

In addition to the on-going Phase 1 clinical trial of IMO-2125 in HCV patients who have not responded to standard of care therapy, we plan to conduct a clinical trial to assess the safety of IMO-2125 in combination with ribavirin in treatment-naïve patients with chronic HCV infection. This clinical trial also will be designed to evaluate the effects of IMO-2125 and ribavirin combination treatment on HCV RNA levels and on parameters of immune system activation.

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.

*Viral Diseases.* In addition to our TLR9 agonists such as IMO-2125, we have identified synthetic RNA-based compounds that mimic viral RNA and are recognized by TLR7 and/or TLR8. We have discovered structural approaches that stabilize these compounds, which we call SIMRA compounds. We have presented immunological activity profiles from preclinical studies in human cell-based assays and *in vivo* in non-human primates in which our TLR7 and/or TLR8 agonist compounds induced immune responses that might be applicable to the treatment of viral infectious diseases.

### *Autoimmune and Inflammatory Diseases*

Systemic lupus erythematosus, or lupus, and rheumatoid arthritis are examples of chronic autoimmune diseases in which the immune system attacks the cells and tissues of the body and causes inflammation and tissue damage. Current therapies include corticosteroids and anti-malarial drugs such as chloroquine. In autoimmune diseases such as lupus and rheumatoid arthritis, the immune system forms antibodies to a molecule that is an appropriate part of the body, also known as a self-antigen. An immune complex is then formed between the self-antigen and the antibody to the self-antigen. Independent researchers have reported that TLR7 and TLR9 may recognize these immune complexes and induce further immune responses to them.

We have identified DNA-based compounds that in preclinical studies have acted as antagonists of TLR7 and TLR9. In studies conducted in mouse models, these antagonists inhibited immune responses mediated through TLR7 and TLR9. We believe that such antagonists may have application in the treatment of autoimmune and inflammatory diseases because they may inhibit TLR7 or TLR9 mediated responses to the immune complex and thereby interfere with the progression of disease symptoms.

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 June 2008, we 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. In August 2008, we selected IMO-3100 as a lead antagonist drug candidate and initiated preclinical development studies in anticipation of submitting an IND by the end of 2009.

### *Oncology*

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. Various mechanisms to increase the immune response to cancer cells have been evaluated by others, including the use of bacterial extracts, *ex vivo* or *in vivo* stimulation of immune cells, and administration of recombinant proteins such as interferons. We believe that agonists of TLRs 7, 8, and 9 can enhance the body's immune response to cancer cells.

We have identified synthetic SIMRA compounds that mimic viral RNA and are recognized by TLR7 and/or TLR8. We have reported data from preclinical studies in human cell-based assays and *in vivo* in non-human primates in which SIMRA compounds induced immune responses. In the reported data, the agonistic activity for TLR7 and TLR8 was dependent on the chemical composition of the SIMRA compounds. We are studying our TLR7 and TLR8 agonists in preclinical models of cancer and have observed antitumor activity as monotherapy and in combination with selected targeted agents. In 2008, we presented data at several scientific conferences on our TLR7 and TLR8 agonists.

We and other researchers have published and presented extensive data on our DNA-based agonists of TLR9 in mouse models of cancer. We have shown in these mouse models that our TLR9 agonists induced an immune response that resulted in antitumor activity. The cascade of immune responses initiated by TLR9 agonists in these studies in mouse models also activated the adaptive immune system and enhanced the recognition of antigens unique to the tumor, which are referred to as tumor-associated antigens.

When our TLR9 agonists were combined in preclinical mouse models with approved anticancer agents, including chemotherapies, antibodies, and newer biologically targeted agents such as inhibitors of proteins involved in cancer cell growth and blood vessel formation, the observed anticancer activity was enhanced beyond that of the anticancer agents alone. We also believe that TLR9 agonists can be combined with tumor-associated antigens to enhance the immune responses to potential cancer vaccine candidates. In preclinical studies conducted by us of some of our TLR9 agonists, enhanced recognition of tumor-associated antigens promoted production of specific antibodies and sensitized immune cells, both of which contribute to an adaptive immune response.

*Collaborative Alliances*

*Oncology — Merck KGaA*

We selected IMO-2055, a synthetic DNA-based TLR9 agonist, as a lead candidate for the treatment of cancer. In December 2007, we entered into an exclusive, worldwide license agreement with Merck KGaA to research, develop, and commercialize products containing our TLR9 agonists, including IMO-2055, for the treatment of cancer, excluding cancer vaccines.

Under our agreement with Merck KGaA, Merck KGaA will determine how to proceed with further clinical development of IMO-2055 in the treatment of cancer. At present, we are conducting on behalf of Merck KGaA a clinical trial of IMO-2055 in combination with Avastin and Tarceva in patients with non-small cell lung cancer, and a clinical trial of IMO-2055 in combination with Erbitux and Camptosar in patients with colorectal cancer.

*Non-small Cell Lung Cancer Avastin and Tarceva Combination Phase 1b Clinical Trial.* In December 2007, we initiated a Phase 1b trial of IMO-2055 in combination with Avastin and Tarceva in non-small cell lung cancer patients whose cancer had progressed during a prior course of standard therapy. The trial is designed 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. IMO-2055 is administered 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 is met. The initial three planned dose levels of IMO-2055 were well tolerated, and patients currently are being recruited at a fourth dose level for the trial, which was designed with a target enrollment of up to 40 patients.

*Colorectal Cancer Erbitux and Camptosar Combination Phase 1b Clinical Trial.* In February 2009, we began dosing the first patient in a Phase 1b clinical trial of IMO-2055 in combination with Erbitux, a recombinant, humanized antibody to epidermal growth factor receptor, and Camptosar, a cytotoxic, chemotherapeutic agent that inhibits topoisomerase I function, in patients with colorectal cancer whose cancer had progressed during a prior course of standard therapy. The trial is designed to assess the safety of the IMO-2055, Erbitux, and Camptosar combination and to determine the recommended dosage of IMO-2055 for potential use in a subsequent Phase 2 clinical trial. Three dose levels of IMO-2055 are being investigated with standard dosages and schedules of Erbitux and Camptosar. IMO-2055 is administered 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. Patients currently are being recruited for the trial, which was designed with a target enrollment of up to 50 patients. We achieved a milestone under our agreement with Merck KGaA upon the dosing of the first patient in the Erbitux/Camptosar clinical trial.

Under our agreement with Merck KGaA, we have agreed with Merck KGaA that we will conduct, on its behalf, the on-going Phase 1b non-small cell lung cancer clinical trial and the on-going Phase 1b colorectal cancer clinical trial. We may initiate and conduct on behalf of Merck KGaA additional clinical trials of IMO-2055. Merck KGaA has agreed to reimburse us for costs associated with the two Phase 1b clinical trials incurred after February 4, 2008, which is the date our agreement with Merck KGaA became effective, and with any additional clinical trials that we may initiate and conduct.

We reported preliminary data from a Phase 2 Stage A clinical trial of IMO-2055 monotherapy in renal cell carcinoma in October 2008. The study contained four arms, comprised of 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 tumor response based on RECIST was not achieved in the study. Median progression-free survival for each of the four arms of the study was 2 months, 3 months, 4 months, and 4 months. IMO-2055 treatment was generally well-tolerated with good dose intensity in all arms of the study. We intend to present data from this clinical trial at a scientific conference in the second half of 2009.

Prior to entering our collaboration with Merck KGaA, we conducted three previous Phase 1 clinical trials of IMO-2055. These studies included a rising dose trial in healthy volunteers, a rising dose trial in advanced cancer patients, and a combination trial of IMO-2055 with gemcitabine and carboplatin in advanced cancer patients.

*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 have conducted with our TLR9 agonists and various antigens have shown improvements in several measures of antigen recognition, such as achievement of higher antibody titers, higher ratios of specific to nonspecific antibodies, and a reduction in the number of doses required to achieve effective antibody titers. As a result, we believe that TLR agonists have the potential to be used as adjuvants in vaccines.

We have entered into a research collaboration with Merck & Co. and have 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. 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. In November 2008, Merck & Co. extended this research collaboration, which was originally for two years, for an additional year to December 2009.

*Asthma and Allergies — Novartis*

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. TLR9 agonists, on the other hand, 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 have shown improvements in multiple indices of allergic conditions. For example, we have presented data from mouse models of allergy that show 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.

We have entered into a research collaboration and option agreement and a separate license, development, and commercialization agreement with Novartis to discover, optimize, develop, and potentially commercialize TLR9 agonists that are identified as potential treatments for asthma and allergies. In September 2008, we achieved a milestone under our Novartis collaboration, related to the initiation of a Phase I clinical trial by Novartis of QAX935, a novel agonist of TLR9.

**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.

*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/or 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;

## Table of Contents

- Merck KGaA agreed to reimburse future development costs for certain of our on-going IMO-2055 clinical trials, which will continue to be conducted by us;
- 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 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/or delaying of the onset or progression of cancer in humans; and
- Develop or commercialize IMO-2055 for use outside treating, curing and/or delaying of 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 Idera is pursuing under its collaboration with Merck & Co.

These restrictions will not limit Idera's 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.

During the period in which we provide follow-on TLR9 agonists, we agreed to form a joint research committee, consisting of an equal number of members from Idera and Merck KGaA, to facilitate our delivery of such compounds.

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 shall continue to pay us royalties 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 has filed an IND application with the FDA and assumes sponsorship of these trials. Under the amendment, Merck KGaA has agreed to reimburse us for costs associated with any additional trials that we may initiate and conduct.

### *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, which collaboration may be extended by Merck & Co. for two additional one-year periods. In November 2008, Merck & Co. extended this research collaboration for an additional one-year period to December 2009. 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;

## [Table of Contents](#)

- 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 royalties on net product sales of vaccines using our TLR agonist technology that are developed and marketed.

Merck & Co. agreed, subject to certain exceptions, that prior to December 8, 2007, it would not sell any of the shares of our common stock acquired by it under the agreement and that, for the duration of the research and collaboration term, its ability to sell such shares will be subject to specified volume limitations.

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. shall continue to pay us royalties 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.

### *Novartis International Pharmaceutical, Ltd.*

In May 2005, we 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. In addition, Novartis may expand the collaboration, if specified conditions are satisfied, to include additional disease areas, excluding oncology and infectious diseases.

The agreements with Novartis are structured in two phases. During the research collaboration phase, we and Novartis agreed to work together to evaluate novel TLR9 agonists from which Novartis may select one or more drug candidates for further development through human clinical trials. Based on the results of the research collaboration, Novartis may elect to implement the commercialization agreement, and, under the license, development and commercialization agreement, complete the development and commercialize one or more of the drug candidates.

Under the terms of the agreements:

- Upon execution of the agreements, Novartis paid us a \$4.0 million upfront license fee;
- Novartis agreed to fund substantially all research activities during the research collaboration phase;

## Table of Contents

- If Novartis elects to exercise its option to develop and commercialize licensed TLR9 agonists in the initial collaboration disease areas, Novartis is potentially obligated to pay us up to \$131.0 million based on the achievement of clinical development, regulatory approval, and annual net sales milestones;
- Novartis is potentially obligated to pay us additional milestone payments if Novartis elects to expand the collaboration to include additional disease areas and then develops and commercializes licensed TLR9 agonists in the additional disease areas based on the achievement of clinical development and regulatory approval milestones;
- Novartis is also obligated to pay us royalties on net sales of all products, if any, commercialized by Novartis, its affiliates and sublicensees; and
- Novartis' license rights under the agreements to products that it elects to develop and commercialize are worldwide, exclusive rights.

We and Novartis initially agreed that the term of the research and collaboration phase would be two years commencing in May 2005. In 2007, Novartis extended our research collaboration by an additional year to May 2008. In connection with this extension, Novartis paid us an additional license fee of \$1.0 million. In March 2008, the term of the research collaboration was further extended until December 31, 2008 in order to allow for QAX935, a novel TLR9 agonist, to be advanced into clinical trials prior to the end of the research and collaboration phase. Our research obligations under the agreement ended in the third quarter of 2008.

Under the agreements, Novartis' obligations to pay us royalties extend, on a product-by-product and country-by-country basis, until the expiration of the patent rights covering the product licensed to Novartis in countries in which there is coverage by licensed patent rights, and, in countries in which there is no coverage by licensed patent rights, until the earlier of the last day of the calendar year in which Novartis loses market exclusivity with respect to a product and the date 10 years after the product's commercial launch.

Novartis may terminate the research collaboration and option agreement without cause upon 90 days written notice to us and the license, development, and commercialization agreement upon 60 days written notice to us. Upon 30 days written notice, either party may terminate the research collaboration and option agreement for a material breach if such breach is not cured within the 30-day notice period, and upon 90 days written notice, either party may terminate the license, development, and commercialization agreement if such breach is not cured within the 90-day notice period. Upon 30 days written notice, either party may terminate the research collaboration and option agreement and/or the license, development, and commercialization agreement upon the other party's filing of bankruptcy.

### **Antisense Technology**

We have been a pioneer in the development of antisense technology. We 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 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.

Currently, we are a party to four collaboration and license agreements involving the use of our antisense technology and specified indications. These agreements include a license agreement with Isis Pharmaceuticals, Inc., or Isis, involving intellectual property for antisense chemistry and delivery.

Under the agreement with Isis, 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 an initial licensing fee and is required to pay us a portion of specified sublicense income it receives from some types of sublicensees of

our patents and patent applications. 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 an initial licensing fee for this license and are obligated to pay Isis a maintenance fee and royalties. 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. 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.

We are also a party to three other license agreements involving the license of our antisense patents and patent applications 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. These agreements typically expire upon the later of the last to expire of the licensed patents or a specified number of years after the first commercial sale of a licensed product. These agreements may be terminated by either party for a material breach, and our collaborators may terminate these agreements at any time for convenience, with written notice.

We are also a party to six royalty-bearing license agreements under which we have 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. Our principal in-license is with University of Massachusetts Medical Center for chemistry and for certain gene targets. Under all of these in-licenses, we are obligated to pay royalties on our net sales of products or processes covered by a valid claim of a licensed patent or patent application. In certain cases, we are required to pay a specified percentage of any sublicense income, and all of these 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 licenses. Additionally, as part of a 2003 interference resolution for one of the licensed patents, a settlement was made enabling us to receive a percentage of the royalty amounts the National Institutes of Health receives for the sale of a product that is covered by such patent.

#### **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 collaborative research agreements may require us to supply certain of our compounds and/or 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 cancelled with limited notice.

#### **Research and Development Expenses**

For the years ended December 31, 2008, 2007 and 2006, we spent approximately \$16.2 million, \$13.2 million and \$12.7 million, respectively, on research and development activities. In 2008, Merck KGaA sponsored approximately \$1.4 million of our research and development activities. In 2008 and 2007, Merck & Co. sponsored approximately \$1.5 million and \$1.1 million, respectively, of our research and development activities. Our collaborators sponsored only a nominal portion of our research and development activities in 2006.

#### **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/or prevent a variety of diseases.

As of February 27, 2009, we owned 61 U.S. patents and U.S. patent applications and 204 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 February 27, 2009, our antisense patent portfolio included 107 U.S. patents and patent applications and 110 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. In addition, the U.S. Patent and Trademark Office 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.

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. 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 a drug, 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.

In addition, the Food and Drug Administration Amendments Act of 2007, or FDAAA, granted significant new powers to the FDA, many of which are aimed at improving the safety of drug products before and after approval. In particular, FDAAA authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information, and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. It also significantly expands the federal government's clinical trial registry and results databank and creates new restrictions on the advertising and promotion of drug products. Under FDAAA, companies that violate these and other provisions of the law are subject to substantial civil monetary penalties, as well as other civil and criminal penalties.

The steps required before a 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;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for each indication;
- 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
- the submission to the FDA of a new drug application, or NDA, or a biologic license application, or BLA.

Nonclinical tests include laboratory evaluation of the product, 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 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 choose to 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 must be reviewed and approved by an independent Institutional Research Board 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 for safety or adverse effects, dosage tolerance, pharmacokinetics, and pharmacologic action; Phase 1b usually involves patients diagnosed with the disease or condition for which the study drug is intended and includes 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.

## [Table of Contents](#)

Phase 1, 2, and 3 testing may not be completed successfully within any specified period, or at all. We, an Institutional Review Board, or the FDA, may suspend or terminate clinical trials at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk. Additional nonclinical toxicology studies are required after clinical trials have begun. 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 patients at the rate we expect;
- 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 and proposed labeling is safe and effective for its intended use. 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, packed 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. The FDA also will inspect the manufacturing facility 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 indications or place other limitations that restrict the commercial application of the product. The FDA may issue a not approvable response to any NDA or BLA we or our collaborators may submit for a variety of reasons, including insufficient evidence of safety and/or efficacy or inadequate manufacturing procedures.

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. The FDA may require additional clinical testing, or Phase 4 clinical trials, to be conducted after initial marketing approval. The FDA may withdraw product approval if compliance with regulatory standards and/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 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. Also, new federal, state, or local government requirements may be established that could delay or prevent regulatory approval of our products under development.

It may take many years and the expenditure of substantial resources to evaluate fully the safety and efficacy of a drug candidate in nonclinical and clinical studies, to qualify appropriate drug 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. 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.

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 present 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 purchase 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, Merck & Co., and Novartis, 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, cancer and asthma and allergies, and as vaccine adjuvants. For all of the disease areas in which we are developing potential therapies, we face competition from other companies developing products involving TLR targeted compounds as well as non-TLR targeted therapies. Some of these non-TLR targeted therapies have been in development or commercialized for years, in some cases by large, well established pharmaceutical companies. Many of the marketed therapies 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 therapies 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.

With respect to the development of products involving stimulation of the immune system, there are a number of companies, both privately and publicly held, that are actively engaged in the discovery, development, and commercialization of products and technologies involving TLR-targeted compounds that compete with our technologies and drug candidates, including compounds targeting TLRs 7, 8 or 9. Our principal competitors developing TLR-targeted compounds include: Pfizer, Inc., which acquired Coley Pharmaceutical Group in November 2007; Dynavax Technologies Corporation; and Anadys Pharmaceutical, Inc. We are also aware that the following companies are developing TLR-targeted compounds: Cytos Biotechnology AG; Eisai, Inc.; GlaxoSmithKline plc; Hemispherx Biopharma, Inc.; Innate Pharma SA; Intercell AG; Opsona Therapeutics Ltd.; and VaxInnate, Inc.

- In infectious diseases, Dynavax Technologies Corporation has an on-going Phase 1 clinical trial with a TLR9 agonist, SD-101, for hepatitis C treatment. Anadys Pharmaceutical, Inc., has an on-going Phase 1 clinical trial with ANA733, a TLR7 agonist prodrug, for hepatitis C treatment.

## Table of Contents

- In autoimmune diseases, Pfizer, Inc., has completed a Phase 1 clinical trial in healthy volunteers with a TLR antagonist, CPG 52364, for the treatment of lupus, and Dynavax Technologies Corporation with its collaborator, GlaxoSmithKline, is developing autoimmune and inflammatory disease therapeutics with their lead TLR inhibitor, DV1079.
- In cancer, Pfizer, Inc., has multiple clinical trials on-going with its TLR9 agonist PF-3512676. In June 2007, Coley Pharmaceutical Group, which has since been acquired by Pfizer, Inc., discontinued certain clinical trials for PF-3512676 in combination with selected cytotoxic agents in lung cancer. Anadys Pharmaceutical, Inc., has announced that is has initiated a Phase 1 clinical trial in solid tumors for its TLR7 agonist prodrug ANA773. VentiRx Pharmaceuticals recently announced commencement of a Phase 1 clinical trial of VTX-2337, a TLR8 agonist for the treatment of cancer.
- In asthma and allergies, Dynavax Technologies Corporation in collaboration with AstraZeneca Pharmaceuticals plc, is conducting preclinical studies of AZD1419, a TLR9 agonist for the treatment of asthma and COPD. Pfizer, Inc., in collaboration with sanofi-aventis Groupe has an ongoing Phase 1 clinical trial in asthma and allergic rhinitis with TLR9 agonist AVE-0675. Cytos Biotechnology has reported results from two Phase 2 clinical trials of its QbG10 technology platform, which includes TLR9 agonists in viral-like particles, in allergic rhinitis and has announced plans to initiate additional Phase 2b trials.
- 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, and Cytos Biotechnology AG.

We recognize that other companies, including large pharmaceutical companies, may be developing or have plans to develop competitive products and technology. 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, marketing and selling approved products.

Competition among these products and therapies will be based, among other things, on product efficacy, safety, reliability, availability, price, and patent position.

The timing of market introduction of our products and competitive products will also affect competition among products. We also 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 an important competitive factor. 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 to secure sufficient capital resources for the often substantial period between technological conception and commercial sales.

### **Employees**

As of February 27, 2009, we employed 37 individuals full-time. Of our 37 employees, 24 are engaged in research and development and 20 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.

**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 and 2008 when our recognition of revenues under license and collaboration agreements resulted in our reporting net income for those years. As of December 31, 2008, we had an accumulated deficit of \$341.2 million. We have incurred losses of \$81.0 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 believe that, based on our current operating plan, our existing cash, cash equivalents, and short-term investments will be sufficient to fund our operations at least through December 31, 2010.

We will need to raise additional funds to operate our business beyond such time, including completing any on-going clinical trials involving IMO-2125 or other drug candidates we may develop. 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, Merck & Co. and Novartis;
- the cost, timing and outcome of regulatory reviews;
- 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.

If we cannot obtain adequate funds, we may 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, or curtail research and development programs for new drug candidates.

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 significantly curtail one or more of our discovery or development programs 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 our lead drug candidate for infectious diseases, IMO-2125, 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 candidate for infectious diseases, IMO-2125. We anticipate that our ability to generate product revenues will depend heavily on the successful development and commercialization of IMO-2125 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;
- demonstration of statistically recognized efficacy in clinical trials;
- ability to combine IMO-2125 safely and successfully with other antiviral agents;
- receipt of marketing approvals from the FDA and equivalent foreign regulatory authorities;
- establishment of commercial manufacturing arrangements with third-party manufacturers;
- the successful commercial launch of the drug candidates, whether alone or in collaboration with other products;
- acceptance of the products by 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.

Our efforts to commercialize IMO-2125 are at an early stage, as we are currently conducting the initial Phase 1 safety clinical trial of this drug candidate in a defined patient population. If we are not successful in commercializing this 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 and other regulatory authorities may not approve any of our potential products for any indication. We may not be able to obtain authority from the FDA or other equivalent foreign regulatory agencies 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 June 2007, Coley Pharmaceutical Group, which since has been acquired by Pfizer, Inc., discontinued four clinical trials in lung cancer for PF-3512676, its investigational TLR9 agonist compound, in combination with cytotoxic chemotherapy. In addition, in January 2007, Coley Pharmaceutical Group announced that it had 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 March 2008 that two investigational new drug applications for its investigational hepatitis B vaccine, HEPLISAV, which includes a proprietary TLR9 agonist, had been placed on clinical hold by the FDA. Dynavax Technologies Corporation also announced in May 2008 discontinuation of the clinical development program for TOLAMBA<sup>®</sup>, which comprises a TLR9 agonist covalently attached to ragweed antigen.

There are to date 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 Institutional Review Boards 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 patients experience serious adverse events or undesirable side effects or are exposed to unacceptable health risks;
- regulators or Institutional Review Boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements and any issues identified through inspections of manufacturing or clinical trial operations or clinical trial sites;

- 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. Employment of such debarred persons, even if inadvertent, may result in delays in the FDA'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.

As an example, in 1997, after reviewing the results from the clinical trial of GEM91, a first generation antisense compound and our lead drug candidate at the time, we determined not to continue the development of GEM91 and suspended clinical trials of this drug candidate.

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 recent approval of two new therapies, Sutent<sup>®</sup> and Nexavar<sup>®</sup>, developed by other companies for treatment of the same patient populations. In addition, in our Phase I clinical trial of IMO-2125 in patients with chronic HCV infection, due to the enrollment procedure, completion of each cohort has taken longer than anticipated. 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 2007, we commenced a Phase 1b clinical trial of IMO-2055 in oncology, and we commenced a Phase 1 clinical trial of IMO-2125 for chronic HCV infection. In 2008, our collaborator Novartis commenced a Phase 1 clinical trial of QAX935, and in 2009 we commenced a second Phase 1b clinical trial of IMO-2055 under our collaboration with Merck KGaA. 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;
- obtaining Institutional Review Board 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 a 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 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. For example, Dynavax Technologies announced in March 2008 that two investigational new drug applications for its investigational hepatitis B vaccine, HEPLISAV, which includes a proprietary TLR9 agonist, had been placed on clinical hold by the FDA. Dynavax Technologies also announced in May 2008 discontinuation of the clinical development program for TOLAMBA, which comprises a TLR9 agonist covalently attached to a ragweed antigen. In addition, Pfizer, Inc. and Anadys Pharmaceuticals, Inc. each have performed early clinical trials of TLR-targeted compounds for the treatment of chronic HCV infection, and both programs have been discontinued. We cannot be certain whether such discontinuations will negatively impact the perception of our TLR technology.

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.***

The biotechnology industry is highly competitive and characterized by rapid and significant technological change. We face, and will continue to face, intense competition from pharmaceutical and biotechnology companies, as well as academic and research institutions and government agencies. Some of these organizations are pursuing products based on technologies similar to our technologies. Other of these organizations have developed and are marketing products, or are pursuing other technological approaches designed to produce products, that are competitive with our drug candidates in the therapeutic effect these competitive products have on diseases targeted by our drug candidates. 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. As examples, the FDA recently approved drugs developed by other companies, Sutent and Nexavar for use in renal cell cancer, which is the indication for which we are evaluating IMO-2055 monotherapy in our Phase 2 clinical trial. Pfizer, Inc., is conducting clinical trials of PF-3512676, a TLR9 agonist for treating cancer. In addition, Dynavax

Technologies Corporation has announced initiation of a clinical trial for its TLR9 agonist 1018 ISS for cancer. Both Pfizer, Inc., and Dynavax Technologies Corporation have clinical programs, either independently or with collaborators, in therapeutic fields other than cancer, such as asthma and allergy treatments and for use as vaccine adjuvants, that also potentially compete with our drug candidates.

Many of our competitors are substantially larger than we are and have greater capital resources, research and development staffs and facilities than we have. In addition, many of our competitors are more experienced than we are in drug discovery, development and commercialization, obtaining regulatory approvals, and drug manufacturing and marketing.

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 leadership for management, 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, 2011, 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 and 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 as part of our internal programs and IMO-2055 on behalf of Merck KGaA.

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.

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

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

In general, submission of materials requesting permission to conduct clinical trials may not result in authorization by the FDA or any equivalent foreign regulatory agency to commence clinical trials. Further, permission to continue ongoing trials may be withdrawn by the FDA or other regulatory agencies at any time after initiation, based on new information available after the initial authorization to commence clinical trials. 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.

Any regulatory approval of a product may contain limitations on the 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, violations of regulatory requirements may result in:

- the regulatory agency's delay in approving, or refusal to approve, an application for marketing of a product;
- restrictions on our products or the manufacturing of our products;
- withdrawal of our products from the market;
- warning letters;
- voluntary or mandatory recall;
- fines;
- suspension or withdrawal of regulatory approvals;
- product seizure;
- 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 gain 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.

## Risks Relating to Collaborators

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

If we do not reach agreements with additional collaborators in the future, we may fail to meet our business objectives. We believe collaborations can provide us with expertise and resources. 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.

The failure of these collaborative alliances could delay our drug development or impair commercialization of our products and could materially harm our business and might accelerate our need for additional capital.

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. Possible future collaborations have risks, including the following:

- disputes may arise in the future with respect to the ownership of rights to technology developed with future collaborators;
- disagreements with future collaborators could delay or terminate the research, development or commercialization of products, or result in litigation or arbitration;
- future 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;
- future collaborators are likely to 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;
- future 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;
- future 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 future collaborators decrease or fail to increase spending relating to such products;
- future collaborators may underfund or not commit sufficient resources to the testing, marketing, distribution or development of our products; and
- future 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.

### *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. In May 2005, we entered into a collaboration with Novartis to discover, develop and potentially commercialize TLR9 agonists that are identified as potential treatments for asthma and allergies. The failure of these collaborations or any others we enter into in the future could delay our drug development or impair commercialization of our products and could materially harm our business and might accelerate our need for additional capital.

The success of our collaborative alliances, if any, will depend heavily on the efforts and activities of our collaborators. Our existing collaborations have risks, including the following:

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

Collaborations with pharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. 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 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. Furthermore, our competitors may independently develop similar technologies or duplicate any technology developed by us. Because of the extensive time required for development, testing, and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thus reducing any advantage provided by the patent.

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

***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.***

We may not have rights under some patents or patent applications related to our products. Third parties may own or control these patents and patent applications in the United States and abroad. Therefore, in some cases, 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 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 in the field of antisense technology we are party to six royalty-bearing license agreements under which we have acquired rights to patents, patent applications and technology of third parties. 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 United States Patent and Trademark Office for certain of our antisense and ribozyme patents. All of these interferences have since been resolved. We are neither practicing nor intending to practice the intellectual property that is associated with any of these interference proceedings.

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

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

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

***Because we have limited manufacturing experience, 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.

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.

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. There are 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 trial of IMO-2125 in patients with chronic HCV infection. 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 requires us to comply with standards, commonly referred to as good clinical practices, for conducting, recording and reporting 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 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 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 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 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.

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. 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,
- 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 9, 2009, the closing sales price of our common stock ranged from a high of \$15.41 per share to a low of \$4.66 per share. The stock market has also experienced significant price and volume fluctuations, particularly within the past year, 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.

**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. Submission of Matters to a Vote of Security Holders**

None.

**Executive Officers of Idera Pharmaceuticals**

The following table sets forth the names, ages and positions of our executive officers as of March 1, 2009:

Name	Age	
Sudhir Agrawal, D. Phil	55	President, Chief Executive Officer, Chief Scientific Officer and Director
Louis J. Arcudi, III	48	Chief Financial Officer, Treasurer and Secretary
Alice S. Bexon, MBChB	39	Vice President of Clinical Development
Timothy M. Sullivan, Ph.D	54	Vice President of Development Programs

*Sudhir Agrawal, D. Phil.*, is our President, Chief Executive Officer and Chief Scientific Officer. He joined us in 1990 and has served as our Chief Scientific Officer since January 1993, our Senior Vice President of Discovery since March 1994, our President from February 2000 to October 2005 and since September 2008, a director since March 1993 and our Chief Executive Officer since August 2004. Prior to his appointment as Chief Scientific Officer, he served as our Principal Research Scientist from February 1990 to January 1993 and as our Vice President of Discovery from December 1991 to January 1993. He served as Acting Chief Executive Officer from February 2000 until September 2001. Prior to joining us, Dr. Agrawal served as a Foundation Scholar at the Worcester Foundation for Experimental Biology from 1987 through 1991 and at the Medical Research Council's Laboratory of Molecular Biology in Cambridge, England from 1985 to 1986. Dr. Agrawal received a D. Phil. in chemistry in 1980 from Allahabad University in India. He has authored more than 290 research papers and reviews. He is a member of the editorial board of several scientific journals. Dr. Agrawal is co-author of more than 400 patents and patent applications worldwide.

*Louis J. Arcudi, III* is our Chief Financial Officer, Treasurer and Secretary. He joined us in December 2007. Prior to joining us, Mr. Arcudi served as Vice President of Finance and Administration and Treasurer for Peptimmune, Inc., a biotechnology company, from 2003 to 2007. From 2000 to 2003 Mr. Arcudi was Senior Director of Finance and Administration at Genzyme Molecular Oncology Corporation, a division of Genzyme Corporation, a biotechnology company. He was Director of Finance Business Planning and Operations International at Genzyme Corporation from 1998 to 2000. Prior to joining Genzyme, he held finance positions with increasing levels of responsibility at Cognex Corporation, a supplier of machine vision systems, Millipore Corporation, a provider of technologies, tools and services for bioscience, research and biopharmaceutical manufacturing, and General Motors Corporation, an automobile manufacturer. Mr. Arcudi received a M.B.A. from Bryant College and a B.S. in accounting and information systems from the University of Southern New Hampshire.

*Alice S. Bexon, MBChB*, joined us in January 2007 as our Vice President of Clinical Development. From April 2001 to January 2007, Dr. Bexon worked for Hoffmann-La Roche, Inc.'s Pharma Division, where she served initially as International Medical Leader for the Oncology Business organization from April 2001 through June 2006 and subsequently as Clinical Science Leader for Pharma Development Medical Oncology from July 2006 to January 2007. Dr. Bexon also served as Medical Director from 1998 to 2001 in the oncology business unit of Sanofi-Synthelabo's French affiliate (now sanofi-aventis), a pharmaceutical company. In addition,

## [Table of Contents](#)

from 1997 to 1998 Dr. Bexon worked for the European Organization for Research and Treatment of Cancer (subsequently NDDO Oncology) in the Netherlands, and in 1997, she worked for Parexel International, a global bio/pharmaceutical services organization, in France. Dr. Bexon received her MBChB (MD equivalent) from Bristol University Medical School in the United Kingdom in 1994 and her full General Medical Council registration to practice medicine the following year. She completed internships in internal medicine and general surgery at Newcastle's Freeman and North Tyneside General Hospitals in the UK and her oncology residency under Professor Jean-Pierre Armand at the Institut Gustave Roussy in Villejuif, France.

*Timothy M. Sullivan, Ph.D.*, has been our Vice President of Development Programs since August 2004. He joined us in 2002 as Senior Director, Preclinical Drug Development. His prior professional experience includes positions as Executive Director of Non-clinical Drug Safety Evaluation for Purdue Pharma L.P., a pharmaceutical company, from 1999 to 2002 and Vice President of Eastern Operations for Oread, Inc., a contract drug development organization, from 1997 to 1999. Prior to 1997, Dr. Sullivan held a variety of technical management roles with other pharmaceutical companies and contract research organizations (Adria, Battelle, Roma Toxicology Centre), and in veterinary medicine (International Minerals & Chemical). Dr. Sullivan earned his B.S. in microbiology from Michigan State University in 1975. His graduate studies were at Purdue University, where he earned a M.S. degree in health physics in 1978 and a Ph.D. in toxicology in 1981.

**PART II.****Item 5. Market For Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities****Market Information**

Our common stock has been listed on the NASDAQ Global Market under the symbol "IDRA" since December 10, 2007. Prior to December 10, 2007, our common stock was listed on the American Stock Exchange under the symbol "IDP."

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.

	<u>High</u>	<u>Low</u>
<b>2007</b>		
First Quarter	\$ 9.50	\$ 5.22
Second Quarter	9.95	6.25
Third Quarter	9.22	6.21
Fourth Quarter	13.10	8.86
<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

As of February 27, 2009, we had approximately 240 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.

**Item 6. Selected Financial Data**

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

	Year Ended December 31,				
	2008	2007	2006	2005	2004
	(In thousands, except per share data)				
<b>Statement of Operations Data:</b>					
Alliance revenue	\$ 26,376	\$ 7,981	\$ 2,421	\$ 2,467	\$ 942
Operating expenses:					
Research and development	16,152	13,195	12,705	11,170	8,249
General and administrative	9,724	9,513	6,276	5,120	5,616
Total operating expenses	25,876	22,708	18,981	16,290	13,865
Income (loss) from operations	500	(14,727)	(16,560)	(13,823)	(12,923)
Other income (expense):					
Investment income, net	1,344	1,668	505	369	217
Interest expense	(92)	(149)	(425)	(252)	(29)
Foreign currency exchange loss	(267)	—	—	—	—
Income (loss) before income taxes	1,485	(13,208)	(16,480)	(13,706)	(12,735)
Income tax benefit (provision)	24	—	(45)	—	—
Net income (loss)	1,509	(13,208)	(16,525)	(13,706)	(12,735)
Accretion of preferred stock dividends	—	—	—	—	(2,676)
Net income (loss) applicable to common stockholders	\$ 1,509	\$ (13,208)	\$ (16,525)	\$ (13,706)	\$ (15,411)
Basic net income (loss) per share	\$ 0.07	\$ (0.62)	\$ (0.99)	\$ (0.99)	\$ (1.03)
Accretion of preferred stock	—	—	—	—	(0.22)
Net income (loss) per share applicable to common stockholders	\$ 0.07	\$ (0.62)	\$ (0.99)	\$ (0.99)	\$ (1.25)
Diluted net income (loss) per share	\$ 0.06	\$ (0.62)	\$ (0.99)	\$ (0.99)	\$ (1.03)
Accretion of preferred stock dividends	—	—	—	—	(0.22)
Net income (loss) per share applicable to common stockholders	\$ 0.06	\$ (0.62)	\$ (0.99)	\$ (0.99)	\$ (1.25)
Shares used in computing basic net income (loss) per common share(1)	22,655	21,221	16,625	13,886	12,364
Shares used in computing diluted net income (loss) per common share(1)	25,331	21,221	16,625	13,886	12,364
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and short-term investments	\$ 55,606	\$ 23,743	\$ 38,187	\$ 8,376	\$ 14,413
Working capital	32,099	15,908	30,984	4,998	13,181
Total assets	59,400	27,714	40,541	9,989	15,391
Capital lease obligations	49	70	10	17	—
Note payable	—	1,143	—	—	—
4% convertible subordinated notes payable	—	—	5,033	5,033	—
Accumulated deficit	(341,225)	(342,734)	(329,526)	(313,000)	(299,294)
Total stockholders’ equity (deficit)	22,167	7,719	12,237	(335)	12,769

(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 have not

been approved for any commercial use. TLRs are specific receptors present in immune system cells that recognize the DNA or RNA of pathogens such as 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, and cancer. IMO-2125, a TLR9 agonist, is our lead drug candidate for infectious diseases. We are conducting a Phase 1 clinical trial of IMO-2125 in patients with chronic hepatitis C virus, or HCV, infection who have not responded to current standard of care therapy. We also plan to conduct a clinical trial of IMO-2125 in combination with ribavirin in treatment-naïve patients with chronic HCV infection. As part of our infectious disease program, we are also evaluating RNA-based compounds that act as agonists of TLR7 and/or TLR8. We have evaluated the mechanism of action of our TLR7 and TLR8 agonist compounds in preclinical studies in human cell-based assays and *in vivo* in non-human primates.

In our autoimmune and inflammatory disease program, we have identified DNA-based compounds that act as antagonists of TLR7 and TLR9. We have evaluated these compounds in mouse models of lupus, rheumatoid arthritis, multiple sclerosis, psoriasis, colitis, and pulmonary inflammation. We have selected IMO-3100 as a lead TLR antagonist drug candidate, and are currently conducting preclinical development studies in anticipation of submitting an Investigational New Drug, or IND, application to the United States Food and Drug Administration, or FDA, by the end of 2009.

Our cancer treatment research program is focused on potential applications of our TLR7 and/or TLR8 agonists. We are studying our TLR7 and TLR8 agonists in preclinical models of cancer and have observed antitumor activity monotherapy and in combination with selected targeted agents.

We are also collaborating with three pharmaceutical companies to advance our TLR-targeted compounds in additional disease areas. We are collaborating with Merck KGaA for cancer treatment excluding cancer vaccines, with Merck & Co., for vaccine adjuvants, and with Novartis International Pharmaceutical, Ltd., or Novartis, for treatment of asthma and allergies. Merck KGaA and Merck & Co. are not related.

At December 31, 2008, we had an accumulated deficit of \$341.2 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 2009, we expect that our research and development expenses will be higher than our research and development expenses in 2008 as we expand our IMO-2125 development program, conduct IND-enabling preclinical evaluations of IMO-3100 and accelerate our early-stage programs 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 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.

We recognize revenue in accordance with Securities and Exchange Commission, or SEC, Staff Accounting Bulletin No. 104, or SAB 104, that requires four basic criteria be met before revenue can be recognized:

- 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
- collectibility 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 collectibility 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, the Company considers whether the components of the arrangement represent separate units of accounting as defined in Emerging Issues Task Force Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*.

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, the period over which the up-front fee is recognized is modified accordingly on a prospective basis.

We recognize revenue from reimbursements received 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. Amounts contractually owed us under these research and development collaboration agreements, including any earned but unbilled receivables, are included 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.

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, revenue is recognized when payment is received.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying balance sheets. Amounts not expected to be recognized within the next twelve months are classified as long-term deferred revenue. As of December 31, 2008, we have short-term and long-term deferred revenue of \$22.3 million and \$12.2 million, respectively, related to our collaborations.

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. Short-term deferred revenue consists of amounts that are expected to be recognized as revenue in the next twelve months. Amounts that we expect will not be recognized prior to the next twelve months are classified as long-term deferred revenue. However, this estimate is based on our collaboration agreements and our current operating plan and, if either should change in the future, we may recognize a different amount of deferred revenue over the next twelve-month period.

The 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 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 adopted Statement of Financial Accounting Standards, or SFAS, No. 123R, *Share-Based Payment*, on January 1, 2006. This statement requires us to recognize all share-based payments to employees as expense in the financial statements based on their fair values. Under SFAS No. 123R, we are required to 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 previously granted stock-based awards outstanding at the date of adoption over the requisite service periods for the individual awards based on the fair value estimated in accordance with the original provisions of SFAS No. 123 adjusted for forfeitures as required by SFAS 123R. As permitted under SFAS 123R, 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 average risk-free interest rate, expected dividend yield, expected life and expected volatility. The assumed risk-free interest rate is 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, the assumed expected option life is (1) based on the average of the option term and the option vesting period for standard options which meet the SEC's Staff Accounting Bulletin 107 criteria for utilizing this simplified method 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, the assumed expected option life is based on actual experience. The expected volatility assumption 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. Existing valuation models, including the Black-Scholes, may not provide reliable measures of the fair values of our stock-based compensation.

*New Accounting Pronouncements*

In December 2007, the Emerging Issues Task Force, or EITF, issued EITF 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*, or EITF 07-1. EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in collaborative arrangements and between participants in the arrangement and third parties. EITF 07-1 states that such participants in collaborative arrangements shall report costs incurred and revenue generated from transactions with *third parties* (that is, parties that do not participate in the arrangement) in each entity's respective income statement. EITF 07-1 is effective for fiscal years beginning after December 15, 2008 and must be applied retrospectively to all prior periods presented for all collaborative arrangements existing as of the effective date. We are currently evaluating the effect of EITF 07-1 on our financial statements.

In June 2007, the EITF issued EITF 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to be Used in Future Research and Development Activities*, or EITF 07-3. EITF 07-3 clarifies the accounting for nonrefundable advance payments for goods or services that will be used or rendered for research and development activities. EITF 07-3 states that such payments should be capitalized and recognized as an expense as the goods are delivered or the related services are performed. If an entity does not expect the goods to be delivered or the services rendered, the capitalized advance payment should be charged to expense. We adopted EITF 07-3 on January 1, 2008. The adoption of EITF 07-3 did not have a material effect on our financial statements for the year ended December 31, 2008.

**Results of Operations**

***Years ended December 31, 2008, 2007 and 2006***

*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, and milestones.

The following is a summary of our alliance revenues:

	Year Ended December 31,			Annual Percentage Change	
	2008	2007	2006	2008/2007	2007/2006
	(In millions)				
License fees	\$21.5	\$6.6	\$2.3	226%	187%
Research and development	2.9	1.1	0.1	164%	1000%
Milestones	2.0	0.3	—	567%	—
Total alliance revenue	<u>\$26.4</u>	<u>\$8.0</u>	<u>\$2.4</u>	230%	233%

Total revenues increased by \$18.4 million, or 230%, from \$8.0 million in 2007 to \$26.4 million in 2008 and increased by approximately \$5.6 million, or 233%, from \$2.4 million in 2006 to \$8.0 million in 2007.

License fees primarily include license fee revenue recognized under our collaborations with Merck KGaA, Merck & Co., and Novartis. License fee revenue is comprised of a portion of upfront license fee payments and a research period extension payment we have received from collaborative alliances with which we are still involved. License fee revenue is recognized over the period of our continuing involvement in the collaboration which generally represents the estimated research period of the agreement. We received a \$40.0 million upfront payment from Merck KGaA in February 2008 of which we received \$39.7 million due to foreign currency exchange rates and

## [Table of Contents](#)

a \$20.0 million upfront payment from Merck & Co. in December 2006. We also received a \$4.0 million upfront payment from Novartis in July 2005 and an additional \$1.0 million payment, to extend the research portion of the agreement, from Novartis in May 2007.

License fees increased by \$14.9 million in 2008 compared to 2007 primarily due to \$15.5 million in license fee revenue we recognized under our collaboration with Merck KGaA, which became effective February 4, 2008. This increase was partially offset by a decrease in license fee revenue recognized under our May 2005 research collaboration with Novartis which decreased by \$0.5 million during 2008 when our research obligations under this collaboration were completed. We also recognized \$5.0 million per year in license fee revenue under our collaboration with Merck & Co. during both 2008 and 2007.

License fees increased by \$4.3 million in 2007 compared to 2006 primarily due to a \$4.7 million increase in license fee revenue recognized under our December 2006 collaboration agreement with Merck & Co. which reflects a full year of license fee revenue recognized during 2007. This increase was partially offset by a \$0.4 million decrease in license fee revenue recognized under our collaboration agreement with Novartis which decreased from \$1.7 million in 2006 to \$1.3 million in 2007.

The increase in research and development revenue in 2008 is due to reimbursable clinical trial costs associated with clinical trials we are conducting under our collaboration agreement with Merck KGaA. The increase in 2008 is also attributable to the purchase of our bulk IMO-2055 drug supply by Merck KGaA at cost and increased reimbursable research costs attributable to expanding research under our Merck & Co. collaboration agreement. The increase in research and development revenues in 2007 is primarily attributable to revenue from research reimbursements under our collaboration agreement with Merck & Co.

The increase in alliance revenue in 2008 is also attributable to milestone revenue of \$1.0 million earned under our collaboration with Novartis relating to an initiation of a Phase 1 clinical trial by Novartis and milestone revenue of \$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 earned a milestone under another collaboration agreement.

### *Research and Development Expenses*

Research and development expenses increased by approximately \$3.0 million, or 23%, from \$13.2 million in 2007 to \$16.2 million in 2008 and increased by approximately \$0.5 million, or 4%, from \$12.7 million in 2006 to \$13.2 million in 2007. 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, increased costs for nonclinical safety studies associated with IMO-3100, increased research expenses under our Merck & Co. agreement, which Merck & Co. has agreed to reimburse, and increased IMO-2055 clinical trial expenses under our Merck KGaA agreement, which Merck KGaA has agreed to reimburse. 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. The increase in research and development expenses from 2006 to 2007 was primarily due to increases in clinical and nonclinical trial costs for IMO-2125, increased research expenses under our Merck & Co. agreement, which Merck & Co. has agreed to reimburse, costs associated with hiring additional drug development employees and stock-based compensation. The 2007 increase was offset, in part, by lower IND-enabling external expenses related to IMO-2125 and a decrease in IMO-2055 external development expenses. The figures in the table below with respect to IMO-2055 exclude all amounts incurred by our collaborator, Merck KGaA.

	Year Ended December 31,			Annual Percentage Change	
	2008	2007	2006	2008/2007	2007/2006
	(In millions)				
IMO-2055 External Development Expense	\$ 1.9	\$ 1.9	\$ 2.9	—	(34)%
IMO-2125 External Development Expense	3.3	1.2	—	175%	—
Other Drug Development Expense	4.5	4.5	5.4	—	(17)%
Basic Discovery Expense	6.5	5.6	4.4	16%	27%
Total Research and Development Expense	<u>\$16.2</u>	<u>\$13.2</u>	<u>\$12.7</u>	23%	4%

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

*IMO-2055 External Development Expenses.* IMO-2055 is a lead compound being developed for oncology applications under our collaboration with Merck KGaA that we entered into in December 2007.

These external expenses include payments to independent contractors and vendors for drug development activities conducted after the initiation of IMO-2055 clinical trials but exclude internal costs such as payroll and overhead expenses. Since 2003, when we commenced clinical development of IMO-2055, we have incurred approximately \$14.5 million in external expenses through December 31, 2008 in connection with IMO-2055.

IMO-2055 external development expenses were consistent between 2007 and 2008 and decreased by \$1.0 million, or 34%, from \$2.9 million in 2006 to \$1.9 million in 2007. In 2008, clinical trial expenses related to our Phase 1 clinical trial of IMO-2055 combined with gemcitabine and carboplatin in patients with solid tumor cancers and our Phase 2 Stage A clinical trial of IMO-2055 as a monotherapy in patients with metastatic or recurrent clear cell renal cancer decreased from 2007. This decrease was offset by increased clinical trial expenses in 2008 associated with the Phase 1b clinical trial of IMO-2055 combined with Avastin and Tarceva in patients with non-small cell lung cancer which was initiated in December 2007 as well as clinical trial expenses associated with the Phase 1b clinical trial of IMO-2055 in combination with Erbitux and Camptosar in patients with colorectal cancer, for which we commenced dosing in February 2009.

The decrease in IMO-2055 expenses in 2007 compared to 2006 was primarily attributable to lower clinical trial expenses as we closed enrollment of our Phase 2 Stage A clinical trial of IMO-2055 as a monotherapy in patients with metastatic or recurrent clear cell renal cancer in June 2007 and of our Phase 1 clinical trial of IMO-2055 combined with gemcitabine and carboplatin in patients with solid tumor cancers in July 2007 and to a decrease in nonclinical safety studies of IMO-2055. These decreases were partially offset by increases associated with our Phase 1b clinical trial of IMO-2055 combined with Avastin and Tarceva in patients with non-small cell lung cancer that we commenced in 2007.

In December 2007, we initiated a Phase 1b clinical trial of IMO-2055 in combination with Avastin and Tarceva in non-small cell lung cancer patients whose cancer had progressed during a prior course of standard therapy. Patients currently are being recruited for this clinical trial, which was designed with a target enrollment of up to 40 patients. In February 2009, we began dosing the first patient in a Phase 1b clinical trial of IMO-2055 in combination with Erbitux and Camptosar in patients with colorectal cancer whose cancer had progressed during a prior course of standard therapy. Patients currently are being recruited for this clinical trial, which was designed with a target enrollment of up to 50 patients.

We reported preliminary data from a Phase 2 Stage A clinical trial of IMO-2055 monotherapy in renal cell carcinoma in October 2008. The study contained four arms, comprised of 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 tumor response based on Response Evaluation Criteria in Solid Tumors, or RECIST, was not achieved in the study. Median progression-free survival for each of the four arms of the study was 2 months, 3 months, 4 months, and 4 months. IMO-2055 treatment was generally well-tolerated with good dose intensity in all arms of the study. We intend to present data from this clinical trial at a scientific conference in the second half of 2009.

Prior to entering our collaboration with Merck KGaA, we conducted three previous Phase 1 clinical trials of IMO-2055. These studies included a rising dose trial in healthy volunteers, a rising dose trial in advanced cancer patients, and a combination trial of IMO-2055 with the chemotherapy agents gemcitabine and carboplatin in advanced cancer patients. We closed enrollment in the Phase 1 clinical trial of IMO-2055 in combination with gemcitabine and carboplatin in July 2007 and reported interim results in September 2007.

We have agreed with Merck KGaA that we will continue to conduct on its behalf the on-going Phase 1b non-small cell lung cancer trial and the on-going Phase 1b colorectal cancer trial. We may initiate and conduct on behalf of Merck KGaA additional clinical trials of IMO-2055. Merck KGaA has agreed to reimburse us for costs associated with these two Phase 1b clinical trials that we incur after February 4, 2008, which is the date our agreement with Merck KGaA became effective, and with any additional trials that we may initiate and conduct. Approximately \$1.0 million of expenses in 2008 related to the Phase 1b combination clinical trial in patients with non-small cell lung cancer and the Phase 1b combination clinical trial in patients with colorectal cancer are reimbursable 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 initially being developed for chronic HCV infection. These external expenses reflect 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 \$4.5 million in external development expenses through December 31, 2008, including costs associated with the initiation of our Phase 1 clinical trial and related nonclinical studies and manufacturing and related process development.

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, which we commenced in September 2007, and costs for nonclinical safety studies of IMO-2125 initiated after the May 2007 submission to the FDA of the IMO-2125 IND application.

In September 2007, we initiated a Phase 1 study of IMO-2125 in patients with chronic HCV infection who have not responded to the current standard of care therapy. We are currently recruiting patients and plan to enroll up to 40 patients in four cohorts at escalating IMO-2125 dose levels, with four weeks of treatment. Of the ten patients per cohort, eight will be randomized to receive IMO-2125 treatment and two will be randomized to receive placebo treatment. The trial is designed to assess the safety of IMO-2125 at each dose level. In addition, the trial is designed to evaluate the effects of IMO-2125 on HCV RNA levels and on parameters of immune system activation.

In this trial, we are enrolling the first five patients per cohort sequentially and allowing each patient to complete at least two weekly injections prior to enrollment of the next patient. Following a safety review of these first five patients in each cohort, the remaining patients of the cohort are enrolled. Due to this enrollment procedure, completion of each cohort has taken longer than anticipated. Currently, we are recruiting patients into the third cohort of the trial. We currently expect interim results from this trial will be available late in 2009.

In addition to the on-going Phase 1 clinical trial of IMO-2125 in HCV patients who have not responded to standard of care therapy, we also plan to conduct a clinical trial to assess the safety of IMO-2125 in combination with ribavirin in treatment-naïve patients with chronic HCV infection. This clinical trial also will be designed to evaluate the effects of IMO-2125 and ribavirin combination treatment on HCV RNA levels and on parameters of immune system activation.

*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.

Other drug development expenses were consistent between 2007 and 2008 and decreased by \$0.9 million, or 17%, from \$5.4 million in 2006 to \$4.5 million in 2007. In 2008, we had a decrease in 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 commencement of clinical development in May 2007 to the IMO-2125 external development expense category shown separately above. This decrease in other drug development expenses in 2008 was partially offset by increased costs associated with nonclinical safety studies associated with IMO-3100 and other compounds. The decrease in 2007 from 2006 was primarily due to decreases in manufacturing and other pre-IND direct external expenses related to IMO-2125 in 2007. The 2007 decrease is computed based on IMO-2125 costs incurred only through April 2007 since costs incurred after the May 2007 submission of the IMO-2125 IND have been shown separately in the above table. The decrease in other drug development expenses during 2007 was offset, in part, by costs associated with the hiring of additional drug development employees, increased stock-based compensation and allocated costs associated with the move to our new facility during the second quarter of 2007. We had direct external expenses of approximately \$0.8 million related to IMO-3100. We had direct external expenses of approximately \$0.4 million and \$2.4 million related to IMO-2125, before we commenced clinical development, for the years ended December 31, 2007 and 2006, respectively.

*Basic Discovery Expenses.* These expenses include our internal and external expenses relating to the discovery and development in our TLR-targeted programs, including agonists and antagonists of TLRs 7, 8 and 9. These expenses reflect payments for laboratory supplies, external research, and professional fees, as well as payroll and overhead. Basic discovery expenses increased by \$0.9 million, or 16%, from \$5.6 million in 2007 to \$6.5 million in 2008 and increased by \$1.2 million, or 27%, from \$4.4 million in 2006 to \$5.6 million in 2007. The increase in expense in 2008 compared to 2007 was primarily attributable to an increase in payroll expenses, expenses, laboratory supplies and allocated costs relating to work under our Merck & Co. collaboration and higher stock-based compensation expense for employees. The increase in 2007 as compared to 2006 was primarily attributable to an increase in payroll expenses, laboratory supplies and allocated costs relating to work under our Merck & Co. collaboration and allocated costs associated with the move to our new facility during the second quarter of 2007.

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 increased by approximately \$0.2 million, or 2%, from \$9.5 million in 2007 to \$9.7 million in 2008 and increased by approximately \$3.2 million, or 51%, from \$6.3 million in 2006 to \$9.5 million in 2007. 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 \$0.2 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. The \$3.2 million increase from 2006 to 2007 primarily reflects increased employee costs, higher stock-based compensation expense for employees and consultants, higher professional fees associated with marketing research and legal services including legal expenses in connection with the Merck KGaA collaboration signed in December 2007, implementation of Sarbanes-Oxley Section 404 requirements, costs associated with the move to our new facility and costs accrued in anticipation of payments to be made to our former Chief Financial Officer under the transition agreement entered into with him in May 2007. The increase in stock compensation expense was \$574,000 in 2007 and was primarily the result of stock compensation expenses associated with non-employee and employee stock options.

#### *Investment Income, Net*

Investment income decreased by approximately \$0.4 million, or 24%, from \$1.7 million in 2007 to \$1.3 million in 2008 and increased by approximately \$1.2 million, or 240%, from \$0.5 million in 2006 to \$1.7 million in 2007. The decrease in 2008 is primarily attributable to lower interest rates on our money market funds and lower yields on our investments. The increase in 2007 is primarily attributable to higher cash and investment balances.

#### *Interest Expense*

Interest expense was consistent from 2007 to 2008 and decreased by approximately \$0.3 million, or 75%, from \$0.4 million in 2006 to \$0.1 million in 2007. The year ended December 31, 2008 reflects 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. The decrease in 2007 was attributable to the conversion of all of our 4% notes, issued in May 2005, in the aggregate principal amount of approximately \$5,033,000 into 706,844 shares of common stock on February 20, 2007. A full year of interest and amortization of deferred financing costs associated with our 4% convertible notes was included in 2006. The decrease in 2007 is partially offset by interest expense associated with our note payable to GE.

#### *Income Tax Expense*

In 2008, we recorded a tax benefit of approximately \$24,000 related to refundable research and experimental tax credits. In 2006, we recorded approximately \$45,000 as income tax expense as a result of income subject to the alternative minimum tax. We did not have income subject to the alternative minimum tax for the years ended 2008 or 2007.

#### *Foreign Currency Exchange Loss*

Foreign currency exchange loss was \$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 years 2007 and 2006.

#### *Net Income (Loss) Applicable to Common Stockholders*

As a result of the factors discussed above, we had net income applicable to common stockholders of \$1.5 million for the year ended December 31, 2008, compared to a net loss applicable to common stockholders of \$13.2 million for the year ended December 31, 2007 and a net loss applicable to common stockholders of \$16.5 million for the year ended December 31, 2006. We have incurred losses of \$81.0 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 \$341.2 million through December 31, 2008. We may incur substantial operating losses in future periods.

#### *Net Operating Loss Carryforwards*

As of December 31, 2008, we had cumulative net operating loss carryforwards of approximately \$275.6 million and \$43.4 million available to reduce federal and state taxable income which expire through 2028 and 2013,

respectively. In addition, we had cumulative federal and state tax credit carryforwards of \$5.5 million and \$4.3 million, respectively, available to reduce federal and state income taxes, which expire through 2028 and 2023, respectively. 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%. We have completed several financings since the effective date of the Tax Reform Act of 1986, which as of December 31, 2008, have resulted in ownership changes in excess of 50%, as defined under the Act and that may significantly limit our ability to utilize our net operating loss and tax credit carryforwards. We have not prepared an analysis to determine the effect of the ownership change limitation on our ability to utilize our net operating loss and tax credit carryforwards. Ownership changes in future periods may place additional limits on our ability to utilize net operating loss and tax credit carryforwards.

## **Liquidity and Capital Resources**

### *Sources of Liquidity*

We require cash to fund our operating expenses, 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.

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

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.

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.

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. 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 \$5.50 per share resulting in an aggregate purchase price of \$10.0 million.

In March 2006, we raised approximately \$9.8 million in gross proceeds from a private placement to institutional investors. In the private placement, we sold for a purchase price of \$3.52 per share 2,769,886 shares of common stock and warrants to purchase 2,077,414 shares of common stock. The warrants have an exercise price of \$5.20 per share, are fully exercisable and will expire if not exercised on or prior to September 24, 2011. The warrants may be exercised by cash payment only. The net proceeds to us from the offering, excluding the proceeds of any future exercise of the warrants, totaled approximately \$8.9 million.

In March 2006, we secured a purchase commitment from an investor to purchase from us up to \$9.8 million of our common stock during the period from June 24, 2006 through December 31, 2006 in up to three drawdowns made by us at our discretion. Prior to December 31, 2006, we drew down the full \$9.8 million through the sale of 1,904,296 shares of common stock at a price of \$5.12 per share resulting in net proceeds to us, excluding the proceeds of any future exercise of the warrants, described below, of approximately \$8.9 million. The agent fees and other costs directly related to securing the commitment amounted to approximately \$0.9 million. As part of the arrangement, we issued warrants to the investor to purchase 761,718 shares of common stock at an exercise price of \$5.92 per share. The warrants are exercisable by cash payment only. The warrants are exercisable at any time on or prior to September 24, 2011. On or after March 24, 2010, we may redeem the warrants for \$0.08 per warrant share following notice to the warrant holders if the closing sales price of the common stock exceeds 250% of the warrant exercise price for 15 consecutive trading days prior to the notice. We may exercise our right to redeem the warrants by providing at least 30 days prior written notice to the holders of the warrants.

#### *Cash Flows*

As of December 31, 2008, we had approximately \$55.6 million in cash and cash equivalents and investments, a net increase of approximately \$31.9 million from December 31, 2007. Operating activities provided \$23.6 million of cash during 2008. The \$23.6 million reflects the \$40.0 million upfront payment less the \$0.3 million foreign currency exchange loss under our agreement with Merck KGaA and our \$1.5 million net income for 2008, as adjusted for non-cash revenue and expenses, including stock-based compensation, depreciation and amortization. It also reflects the changes in deferred revenue associated with revenue recognition under our collaborative alliances and changes in our accounts receivable, prepaid expenses and accounts payable and accrued expenses.

The net cash provided by investing activities during 2008 of \$0.2 million reflects our purchase of approximately \$23.0 million in securities offset by the proceeds of approximately \$23.6 million from securities that matured in 2008. The net cash provided by investing activities also reflects a \$0.4 million investment in laboratory, office and computer equipment.

The net cash provided by financing activities during 2008 of \$8.8 million primarily reflects the \$10.0 million in proceeds received from the exercise of common stock options, warrants and employee stock purchases during 2008 offset by the \$1.1 million repayment of our promissory note.

*Funding Requirements*

We have incurred operating losses in all fiscal years except 2002 and 2008, and we had an accumulated deficit of \$341.2 million at December 31, 2008. We had cash, cash equivalents and short-term investments of \$55.6 million at December 31, 2008. We believe that based on our current operating plan our existing cash, cash equivalents and short-term investments will be sufficient to fund our operations at least through December 31, 2010. 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 believe that the key factors that will affect our internal and external sources of cash are:

- the success of our clinical and preclinical development programs;
- the success of our existing strategic collaborations with Merck KGaA, Merck & Co. and Novartis;
- the cost, timing and outcome of regulatory reviews;
- 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 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, 2008, our contractual commitments were as follows:

Contractual Obligations	Payments Due by Period				
	Total	Less than 1 year	1-3 years (In thousands)	3-5 years	After 5 years
Operating Lease Commitments	\$7,126	\$ 1,219	\$ 2,567	\$ 2,749	\$ 591
Capital Lease Commitments	49	18	31	—	—
<b>Total</b>	<b>\$7,175</b>	<b>\$ 1,237</b>	<b>\$ 2,598</b>	<b>\$ 2,749</b>	<b>\$ 591</b>

Our only material lease commitment relates to our facility in Cambridge, Massachusetts. Under our 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, 2008, we have no off balance sheet arrangements.

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

As of December 31, 2008, we had approximately \$0.4 million of receivables payable in Euros. We had no other assets and liabilities related to nondollar-denominated currencies as of December 31, 2008.

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

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

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

All financial statements required to be filed hereunder are filed as listed under Item 15(a) 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, 2008. The information for each of these quarters is unaudited, but has been prepared on the same basis as the audited financial statements appearing elsewhere in this Annual Report on Form 10-K. In our opinion, all necessary adjustments, consisting only of normal recurring adjustments, have been made to present fairly the unaudited quarterly results when read in conjunction with the audited financial statements and the notes thereto appearing elsewhere in this document. These operating results are not necessarily indicative of the results of operations that may be expected for any future period.

	Three Months Ended							
	Dec. 31, 2008	Sep. 30, 2008	Jun. 30, 2008	Mar. 31, 2008	Dec. 31, 2007	Sep. 30, 2007	Jun. 30, 2007	Mar. 31, 2007
(In thousands, except per share data)								
<b>Statement of Operations Data:</b>								
Alliance revenues	\$ 6,241	\$ 7,498	\$ 7,865	\$ 4,772	\$ 2,233	\$ 1,970	\$ 1,949	\$ 1,829
Operating expenses:								
Research and development(1)	4,286	3,580	3,752	4,534	3,907	3,479	2,990	2,819
General and administrative	1,772	2,304	3,232	2,416	3,144	2,033	2,383	1,953
Total operating expenses	<u>6,058</u>	<u>5,884</u>	<u>6,984</u>	<u>6,950</u>	<u>7,051</u>	<u>5,512</u>	<u>5,373</u>	<u>4,772</u>
Income (loss) from operations	183	1,614	881	(2,178)	(4,818)	(3,542)	(3,424)	(2,943)
Investment income	159	369	410	406	346	416	429	477
Interest expense	(2)	(3)	(5)	(82)	(34)	(40)	(13)	(62)
Foreign currency exchange loss	—	—	—	(267)	—	—	—	—
Income (loss) before income taxes	340	1,980	1,286	(2,121)	(4,506)	(3,166)	(3,008)	(2,528)
Income tax benefit (provision)	24	—	50	(50)	—	—	—	—
Net income (loss) applicable to common stockholders	<u>\$ 364</u>	<u>\$ 1,980</u>	<u>\$ 1,336</u>	<u>\$ (2,171)</u>	<u>\$ (4,506)</u>	<u>\$ (3,166)</u>	<u>\$ (3,008)</u>	<u>\$ (2,528)</u>
Basic net income (loss) per share applicable to common stockholders	<u>\$ 0.02</u>	<u>\$ 0.09</u>	<u>\$ 0.06</u>	<u>\$ (0.10)</u>	<u>\$ (0.21)</u>	<u>\$ (0.15)</u>	<u>\$ (0.14)</u>	<u>\$ (0.12)</u>
Diluted net income (loss) per share applicable to common stockholders	<u>\$ 0.01</u>	<u>\$ 0.08</u>	<u>\$ 0.05</u>	<u>\$ (0.10)</u>	<u>\$ (0.21)</u>	<u>\$ (0.15)</u>	<u>\$ (0.14)</u>	<u>\$ (0.12)</u>
Shares used in computing basic income (loss) per common share(2)	<u>23,331</u>	<u>23,022</u>	<u>22,481</u>	<u>21,899</u>	<u>21,485</u>	<u>21,346</u>	<u>21,254</u>	<u>20,787</u>
Shares used in computing diluted income (loss) per common share(2)	<u>24,822</u>	<u>25,779</u>	<u>25,507</u>	<u>21,899</u>	<u>21,485</u>	<u>21,346</u>	<u>21,254</u>	<u>20,787</u>

- (1) As discussed in Note 2(o), we adopted EITF 07-3 on January 1, 2008. The adoption of EITF 07-3 decreased research and development expense and increased net income by \$300,000 during the three months ended September 30, 2008 and increased research and development expense and decreased net income by \$300,000 during the three months ended December 31, 2008. The adoption of EITF 07-3 increased basic earnings per share and diluted earnings per share by \$0.02 per share and \$0.01 per share, respectively, during the three months ended September 30, 2008 and decreased basic earnings per share and diluted earnings per share by \$0.01 per share and \$0.02 per share, respectively, during the three months ended December 31, 2008.
- (2) Computed on the basis described in Note 13 of notes to financial statements appearing elsewhere in this Annual Report on Form 10-K.

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

None.

**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, 2008. 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, 2008, 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 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, 2008. 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, 2008, 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.

**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, 2008, 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, 2008, 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, 2008 and 2007, and the related statements of operations, Stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2008 of Idera Pharmaceuticals, Inc. and our report dated March 9, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts  
March 9, 2009

**c) Changes in Internal Controls.**

No change in our internal control over financial reporting occurred during the fiscal year ending December 31, 2008 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information.**

None.

**PART III.**

The response to the Part III items incorporate by reference certain sections of our Proxy Statement for our annual meeting of stockholders to be held on June 16, 2009. Our 2009 Proxy Statement will be filed within 120 days of December 31, 2008.

**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 “Investor Center — Code of Ethics” section of our website, which is located at [www.iderapharma.com](http://www.iderapharma.com). We intend to satisfy the disclosure requirements under Item 10 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 2009 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. See also Part I of this Annual Report on 10-K under the caption “Executive Officers of Idera Pharmaceuticals,” which is incorporated herein by reference.

**Item 11. Executive Compensation**

The responses to this item are contained in the 2009 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 2009 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 2009 Proxy Statement under the caption “Equity Compensation Plan Information.”

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

The response to this item is contained in the 2009 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 2009 Proxy Statement under the caption “Independent Registered Public Accounting Firm Fees,” which section is incorporated herein by reference.

**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, 2008 and 2007	F-3
Statements of Operations for the years ended December 31, 2008, 2007 and 2006	F-4
Statements of Stockholders' Equity (Deficit) for the years ended December 31, 2008, 2007 and 2006	F-5
Statements of Cash Flows for the years ended December 31, 2008, 2007 and 2006	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.



**IDERA PHARMACEUTICALS, INC.**  
**INDEX TO FINANCIAL STATEMENTS**  
**December 31, 2008**

	<u>Page</u>
<a href="#">Report of Independent Registered Public Accounting Firm</a>	F-2
<a href="#">Balance Sheets</a>	F-3
<a href="#">Statements of Operations</a>	F-4
<a href="#">Statements of Stockholders' Equity (Deficit)</a>	F-5
<a href="#">Statements of Cash Flows</a>	F-6
<a href="#">Notes to Financial Statements</a>	F-7

**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, 2008 and 2007, and the related statements of operations, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2008. 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, 2008 and 2007, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2008, 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 Pharmaceutical, Inc.'s internal control over financial reporting as of December 31, 2008, 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 9, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts  
March 9, 2009

**IDERA PHARMACEUTICALS, INC.**

**BALANCE SHEETS**

<b>(In thousands, except per share amounts)</b>	<b>December 31, 2008</b>	<b>December 31, 2007</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 45,165	\$ 12,588
Short-term investments	10,441	11,155
Receivables	474	293
Prepaid expenses and other current assets	876	991
<b>Total current assets</b>	<b>56,956</b>	<b>25,027</b>
Property and equipment, net	1,824	1,964
Non-current portion of prepaid expenses	104	104
Restricted cash	516	619
<b>Total assets</b>	<b>\$ 59,400</b>	<b>\$ 27,714</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,345	\$ 1,177
Accrued expenses	1,199	1,745
Current portion of capital lease	18	20
Current portion of note payable	—	266
Current portion of deferred revenue	22,295	5,911
<b>Total current liabilities</b>	<b>24,857</b>	<b>9,119</b>
Capital lease obligation, net of current portion	31	50
Note payable, net of current portion	—	877
Deferred revenue, net of current portion	12,165	9,874
Other liabilities	180	75
<b>Total liabilities</b>	<b>37,233</b>	<b>19,995</b>
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, 2008 and 2007	—	—
Common stock, \$0.001 par value, Authorized — 70,000 and 40,000 shares at December 31, 2008 and 2007, respectively Issued and outstanding — 23,413 and 21,569 shares at December 31, 2008 and 2007, respectively	23	22
Additional paid-in capital	363,405	350,423
Accumulated deficit	(341,225)	(342,734)
Accumulated other comprehensive (loss) income	(36)	8
<b>Total stockholders' equity</b>	<b>22,167</b>	<b>7,719</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 59,400</b>	<b>\$ 27,714</b>

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

**IDERA PHARMACEUTICALS, INC.**  
**STATEMENTS OF OPERATIONS**

(In thousands, except per share amounts)	Years Ended December 31,		
	2008	2007	2006
Alliance revenue	\$ 26,376	\$ 7,981	\$ 2,421
Operating expenses:			
Research and development	16,152	13,195	12,705
General and administrative	9,724	9,513	6,276
Total operating expenses	25,876	22,708	18,981
Income (loss) from operations	500	(14,727)	(16,560)
Other income (expense):			
Investment income, net	1,344	1,668	505
Interest expense	(92)	(149)	(425)
Foreign currency exchange loss	(267)	—	—
Income (loss) before income taxes	1,485	(13,208)	(16,480)
Income tax benefit (provision)	24	—	(45)
Net income (loss)	\$ 1,509	\$ (13,208)	\$ (16,525)
Income (loss) per common share (Note 13):			
Basic	\$ 0.07	\$ (0.62)	\$ (0.99)
Diluted	\$ 0.06	\$ (0.62)	\$ (0.99)
Shares used in computing basic income (loss) per common share	22,655	21,221	16,625
Shares used in computing diluted income (loss) per common share	25,331	21,221	16,625

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

**IDERA PHARMACEUTICALS, INC.**  
**STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)**

(In thousands)	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive (Loss)/Income	Total Stockholders' Equity (Deficit)
	Number of Shares	\$0.001 Par Value				
<b>Balance, December 31, 2005</b>	13,928	\$ 14	\$312,664	\$ (313,001)	\$ (11)	\$ (334)
Sale of common stock	6,492	6	27,782	—	—	27,788
Exercise of common stock options and employee stock purchases	32	—	108	—	—	108
Issuance of stock for services	6	—	27	—	—	27
Non-employee stock option expense	—	—	238	—	—	238
Stock-based compensation	—	—	924	—	—	924
Comprehensive income (loss):						
Unrealized gain on marketable securities	—	—	—	—	11	11
Net loss	—	—	—	(16,525)	—	(16,525)
Total comprehensive loss	—	—	—	—	—	(16,514)
<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

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

**IDERA PHARMACEUTICALS, INC.**  
**STATEMENTS OF CASH FLOWS**

(in thousands)	Years Ended December 31,		
	2008	2007	2006
<b>Cash Flows from Operating Activities:</b>			
Net income (loss)	\$ 1,509	\$ (13,208)	\$ (16,525)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities —			
Loss from disposition of assets	2	6	—
Non-employee stock option expense	398	519	238
Stock-based compensation	2,628	1,582	924
Amortization expense	36	(46)	(19)
Depreciation expense	530	364	247
Issuance of stock for services	22	44	27
Amortization of deferred financing costs	—	31	223
Non cash interest expense	—	—	34
Changes in operating assets and liabilities —			
Receivables	(181)	(230)	(222)
Prepaid expenses and other current assets	218	(264)	82
Accounts payable, accrued expenses, and other liabilities	(273)	899	(251)
Deferred revenue	18,675	(5,457)	17,841
Net cash provided by (used in) operating activities	23,564	(15,760)	2,599
<b>Cash Flows from Investing Activities:</b>			
Purchases of available-for-sale securities	(22,985)	(50,545)	(26,769)
Proceeds from sale of available-for-sale securities	—	37,814	7,975
Proceeds from maturities of available-for-sale securities	23,620	15,220	12,625
Increase in restricted cash	—	—	(619)
Purchases of property and equipment	(393)	(1,632)	(89)
Net cash provided by (used in) investing activities	242	857	(6,877)
<b>Cash Flows from Financing Activities:</b>			
Sale of common stock and warrants, net of issuance costs	—	—	27,788
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	10,030	1,770	108
Repurchase of common stock	(95)	—	—
Payments on capital lease	(21)	(18)	(7)
Net cash provided by financing activities	8,771	2,895	27,889
Net increase (decrease) in cash and cash equivalents	32,577	(12,008)	23,611
Cash and cash equivalents, beginning of period	12,588	24,596	985
Cash and cash equivalents, end of period	\$ 45,165	\$ 12,588	\$ 24,596

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

**IDERA PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS**  
**December 31, 2008**

**(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 pathogens such as 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 our 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 Idera 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, and cancer. IMO-2125, a TLR9 agonist, is the Company’s lead drug candidate for infectious diseases. The Company is conducting a Phase 1 clinical trial of IMO-2125 in patients with chronic hepatitis C virus, or HCV, infection who have not responded to current standard of care therapy. The trial is designed to assess the safety of IMO-2125. In addition, the trial is designed to evaluate the effects of IMO-2125 on HCV RNA levels and on parameters of immune system activation. The Company also plans to conduct a clinical trial of IMO-2125 to assess the safety of IMO-2125 in combination with ribavirin in treatment-naïve patients with chronic HCV infection. This clinical trial also will evaluate the effects of IMO-2125 and ribavirin combination treatment on HCV RNA levels and on parameters of immune system activation.

As part of the Company’s infectious disease program, it is also evaluating RNA-based compounds that act as agonists of TLR7 and/or TLR8. The Company refers to its TLR7 and TLR8 agonists as stabilized immune modulatory RNA, or SIMRA, compounds. It is evaluating the mechanism of action of its SIMRA compounds in preclinical studies in human cell-based assays and *in vivo* in non-human primates.

In the Company’s autoimmune and inflammatory disease program, it has identified DNA-based compounds that act as antagonists of TLR7 and TLR9. The Company has evaluated these compounds in mouse models of lupus, rheumatoid arthritis, multiple sclerosis, psoriasis, colitis, and pulmonary inflammation. Idera has selected IMO-3100 as a lead TLR antagonist drug candidate, and is currently conducting preclinical development studies in anticipation of submitting an Investigational New Drug, or IND, application to the United States Food and Drug Administration, or FDA, by the end of 2009. The Company has formed an Autoimmune Disease Scientific Advisory Board to assist it in the clinical development strategy for IMO-3100 and other antagonist candidates in autoimmune and inflammatory diseases.

The Company’s cancer treatment research program is focused on potential applications of its TLR7 and/or TLR8 agonists. The Company is studying its TLR7 and TLR8 agonists in preclinical models of cancer and has observed antitumor activity as monotherapy and in combination with selected targeted agents.

Idera is also collaborating with three pharmaceutical companies to advance its TLR-targeted compounds in additional disease areas. The Company is collaborating with Merck KGaA for cancer treatment excluding cancer vaccines, with Merck & Co., Inc., or Merck & Co., for vaccine adjuvants, and with Novartis International Pharmaceutical, Ltd., or Novartis, for treatment of asthma and allergies. Merck KGaA and Merck & Co. are not related.

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

The Company has incurred operating losses in all fiscal years except 2002 and 2008 and had an accumulated deficit of \$341.2 million at December 31, 2008. The Company may incur substantial operating losses in future periods. The Company does not expect to generate significant funds internally until it successfully completes development and obtains marketing approval for its products, either alone or in collaborations with third parties, which the Company expects will take a number of years. In order to commercialize its therapeutic products, the Company needs to address a number of technological challenges and to comply with comprehensive regulatory requirements.

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.

*(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, 2008 and 2007 consisted of cash and money market funds.

The Company accounts for investments in accordance with Statement of Financial Accounting Standards (SFAS) No. 115, *Accounting for Certain Investments in Debt and Equity Securities* (SFAS No. 115). Management determines the appropriate classification of marketable securities at the time of purchase. In accordance with SFAS No. 115, 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) income" on the accompanying balance sheets. The amortization of premiums and accretion of discounts, and any realized gains and losses and declines in value judged to be other than temporary, and interest and dividends for all available-for-sale securities are included in "Investment income, net" on the accompanying statements of operations. The Company had no "held-to-maturity" investments, as defined by SFAS No. 115, at either December 31, 2008 or 2007. 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 2008, 2007 or 2006. 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, 2008, 2007 and 2006.

The Company had no long-term investments as of December 31, 2008 and 2007. The Company had no auction rate securities as of December 31, 2008 and 2007.

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

*(d) Restricted Cash*

As part of the operating lease entered into by the Company in October 2006 (see Note 10(a)), the Company was required to restrict \$619,000 of cash for a security deposit. These funds are held in certificates of deposit securing a line of credit for the lessor. The restricted cash is expected to be reduced by approximately \$103,000 upon each of the second, third and fourth anniversaries of the lease commencement date of June 2007, 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, as follows:

<u>Asset Classification</u>	<u>Estimated Useful Life</u>
Leasehold improvements	Shorter of the useful life or the life of lease
Laboratory equipment and other	3 — 5 years

*(f) Revenue Recognition*

The Company's revenue recognition policy complies with Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition*. Alliance revenues are comprised of payments under various collaboration and licensing agreements for research and development, including reimbursement of third-party expenses, milestone payments, license fees, sublicense fees, and royalty payments. When evaluating multiple element arrangements, the Company considers whether the components of the arrangement represent separate units of accounting as defined in Emerging Issues Task Force Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*.

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 estimated continuing involvement under the research arrangement. If the estimated period of continuing involvement is subsequently modified, the period over which the up-front fee is recognized is modified accordingly on a prospective basis.

The Company recognizes revenue from reimbursements received in connection with research and development collaboration agreements as related research and development costs are incurred, and contractual services are performed, provided collectability is reasonably assured. Amounts contractually owed under these research and development collaboration agreements, including any earned but unbilled receivables, are included in trade accounts receivable in the accompanying balance sheets. The Company's principal costs under these agreements are generally for the Company's personnel and related expenses of conducting research and development, as well as for research and development performed by outside contractors or consultants.

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, the Company 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, revenue is recognized when payment is received.

**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 accompanying balance sheets. Amounts not expected to be recognized within the next twelve months are classified as long-term deferred revenue. As of December 31, 2008, the Company has short-term and long-term deferred revenue of \$22.3 million and \$12.2 million, respectively, related to its collaborations.

Although the Company follows detailed guidelines in measuring revenue, certain judgments affect the application of the Company's 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. Short-term deferred revenue consists of amounts that are expected to be recognized as revenue in the next twelve months. Amounts that the Company does not expect to recognize prior to the next twelve months are classified as long-term deferred revenue. However, this estimate is based on the Company's collaboration agreements and its current operating plan and, if either should change in the future, the Company may recognize a different amount of deferred revenue over the next twelve-month period.

The 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 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 record in future periods.

*(g) Financial Instruments*

SFAS No. 107, *Disclosures About Fair Value of Financial Instruments*, requires disclosure of the estimated fair values of financial instruments. The Company's financial instruments consist of cash and cash equivalents, short-term investments and receivables. The estimated fair values of these financial instruments approximates their carrying values as of December 31, 2008 and 2007, respectively. As discussed in Note 2(n) the estimated fair values have been determined in accordance with the SFAS No. 157, *Fair Value Measurements*. As of December 31, 2008 and 2007, the Company does not have any derivatives or any other financial instruments as defined by SFAS No. 133, *Accounting for Derivative and Hedging Instruments*.

*(h) Comprehensive Income (Loss)*

The Company applies SFAS No. 130, *Reporting Comprehensive Income*. 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 nonowner sources. Comprehensive income (loss) for the years ended December 31, 2008, 2007 and 2006 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*

The Company applies SFAS No. 128, *Earnings per Share* (SFAS No. 128). Under SFAS No. 128, 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 under SFAS No. 128. Diluted net loss per common share is the same as basic net loss per common share for the years ended December 31, 2007 and 2006 as the effects of the Company's potential common stock equivalents are antidilutive (see Note 13).

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

*(j) Segment Reporting*

SFAS No. 131, *Disclosures About Segments of an Enterprise and Related Information* (SFAS No. 131), establishes standards for reporting information regarding operating segments in annual financial statements and requires selected information for those segments to be presented in interim financial reports issued to stockholders. SFAS No. 131 also establishes standards for related disclosures about products and services and geographic areas.

To date, the Company has viewed its operations and manages its business as one operating segment. Accordingly, the Company operates in one segment, which is the business of discovering and developing novel therapeutics that modulate immune responses through TLRs. As a result, the financial information disclosed herein represents all of the material financial information related to the Company's principal operating segment. For all of the periods presented, all of the Company's revenues were generated in the United States. As of December 31, 2008 and 2007, all assets were located in the United States.

*(k) Stock-Based Compensation*

The Company applies SFAS No. 123R, *Share-Based Payment* (SFAS No. 123R). This statement requires the Company to recognize all share-based payments to employees in the financial statements based on their fair values. Under SFAS No. 123R, the Company is required to record compensation expense over an award's requisite service 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. For the years ended December 31, 2008, 2007 and 2006, the Company included charges of approximately \$2,628,000, \$1,582,000 and \$924,000, respectively, in its statement of operations representing the stock compensation expense computed in accordance with SFAS No. 123R.

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 assumptions used to estimate the weighted average grant date fair values of options granted to employees and the weighted average exercise prices of options granted to employees during the years ended December 31, 2008, 2007, and 2006 are as follows:

	<u>2008</u>	<u>2007</u>	<u>2006</u>
Average risk free interest rate	2.4%	4.4%	4.6%
Expected dividend yield	—	—	—
Expected lives (years)	4.9	5.9	6.0
Expected volatility	66%	70%	94%
Weighted average grant date fair value of options granted during the period (per share)	\$ 6.28	\$ 5.81	\$ 3.77
Weighted average exercise price of options granted during the period (per share)	\$ 11.18	\$ 8.86	\$ 4.83

All options granted during the three years ended December 31, 2008 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 \$2,244,000, \$551,000 and \$12,000 during 2008, 2007 and 2006, respectively. The fair value of options that vested amounted to \$2,896,000, \$1,609,000 and \$1,144,000 during 2008, 2007, and 2006, respectively. As of December 31, 2008, there was \$7,831,000 of unrecognized compensation cost related to unvested stock-based compensation arrangements, which is expected to be recognized over a weighted average period of 3.0 years.

The Company also awarded non-employee stock options to purchase 87,250, 5,000 and 130,000 shares of common stock during 2008, 2007 and 2006, respectively. These options had Black-Scholes fair values of

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

\$1,055,000, \$34,000 and \$591,000 at the time of grant during 2008, 2007 and 2006, respectively based on the following assumptions:

	<u>2008</u>	<u>2007</u>	<u>2006</u>
Average risk free interest rate	3.9%	4.8%	4.6%
Expected dividend yield	—	—	—
Expected lives (years)	10.0	10.0	10.0
Expected volatility	94%	98%	95%

The fair value of the nonvested portion of the non-employee options will be remeasured each quarter in accordance with EITF No. 96-18, *Accounting for Equity Instruments That Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services* (EITF No. 96-18). Approximately \$398,000, \$519,000 and \$238,000 was recorded as an expense for these options in 2008, 2007 and 2006, respectively.

There was approximately \$53,000, \$27,000 and \$24,000 in compensation expense related to the Company's 1995 Employee Stock Purchase Plan during 2008, 2007 and 2006, respectively. This expense was computed based on the Black-Scholes option pricing model and the following assumptions:

	<u>2008</u>	<u>2007</u>	<u>2006</u>
Average risk free interest rate	2.1%	4.7%	4.6%
Expected dividend yield	—	—	—
Expected lives (months)	3.0	3.0	3.0
Expected volatility	70%	72%	58%

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 and \$73,000 of amortization was expensed during 2008 and 2007, respectively. 20,833 shares subject to this restricted stock grant vested during 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 2008, Merck KGaA sponsored approximately \$1.4 million of our research and development activities. In 2008 and 2007, Merck & Co. sponsored approximately \$1.5 million and \$1.1 million, respectively, of the Company's research and development activities. Collaborators sponsored only a nominal portion of the Company's research and development activities in 2006.

*(m) Concentration of Credit Risk*

Financial instruments that subject the Company to credit risk primarily consist of cash and cash equivalents and short-term 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, 2008, approximately 99% of the Company's cash, cash equivalents, and investments are held at one financial institution.

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

(n) *Fair Value of Assets and Liabilities*

In September 2006, the Financial Accounting Standards Board (FASB) issued Statement SFAS No. 157, *Fair Value Measurements*, effective for financial statements issued for fiscal years beginning after November 15, 2007. SFAS No. 157 replaces multiple existing definitions of fair value with a single definition, establishes a consistent framework for measuring fair value and expands financial statement disclosures regarding fair value measurements. This Statement applies only to fair value measurements that already are required or permitted by other accounting standards and does not require any new fair value measurements. The Company's adoption of SFAS No. 157 in the first quarter of 2008 did not have a material impact on the Company's financial position or results of operations.

In accordance with the provisions of SFAS No. 157, 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. SFAS No. 157 prioritizes the assumptions that market participants would use in pricing the asset or liability (the "inputs") into a three-tier fair value hierarchy. This fair value hierarchy gives the highest priority (Level 1) to quoted prices in active markets for identical assets or liabilities and the lowest priority (Level 3) to unobservable inputs in which little or no market data exists, requiring companies to develop their own assumptions. Observable inputs that do not meet the criteria of Level 1, and include quoted prices for similar assets or liabilities in active markets or quoted prices for identical assets and liabilities in markets that are not active, are categorized as Level 2. Level 3 inputs are those that reflect the Company's estimates about the assumptions market participants would use in pricing the asset or liability, based on the best information available in the circumstances. Valuation techniques for assets and liabilities measured using Level 3 inputs may include unobservable inputs such as projections, estimates and management's interpretation of current market data. These unobservable Level 3 inputs are only utilized to the extent that observable inputs are not available or cost-effective to obtain.

The table below presents the assets and liabilities measured at fair value on a recurring basis at December 31, 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>Assets</b>				
Money market funds	\$ 44,842	\$ 44,842	\$ —	\$ —
Investments	10,441	—	10,441	—
<b>Total</b>	<b>\$55,283</b>	<b>\$ 44,842</b>	<b>\$ 10,441</b>	<b>\$ —</b>
<b>Liabilities</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ —</b>

The money market funds are classified as Level 1 since they are actively traded daily at \$1.00 per share.

The fair value of short-term investments 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 also adopted the provisions of SFAS No. 159 *The Fair Value Option for Financial Assets and Financial Liabilities — Including an Amendment of FASB Statement No. 115* in the first quarter of 2008. SFAS No. 159 allows companies to choose to measure eligible assets and liabilities at fair value with changes in value recognized in earnings. Fair value treatment may be elected either upon initial recognition of an eligible asset or liability or, for an existing asset or liability, if an event triggers a new basis of accounting. The Company did not elect to re-measure any of its existing financial assets or liabilities under the provisions of SFAS No. 159.

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

*(o) New Accounting Pronouncements*

In December 2007, the Emerging Issues Task Force (“EITF”) issued EITF 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property* (“EITF 07-1”). EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in collaborative arrangements and between participants in the arrangement and third parties. EITF 07-1 states that such participants in collaborative arrangements shall report costs incurred and revenue generated from transactions with *third parties* (that is, parties that do not participate in the arrangement) in each entity’s respective income statement. EITF 07-1 is effective for fiscal years beginning after December 15, 2008 and must be applied retrospectively to all prior periods presented for all collaborative arrangements existing as of the effective date. The Company is currently evaluating the effect of EITF 07-1 on its financial statements.

In June 2007, the EITF issued EITF 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to be Used in Future Research and Development Activities* (“EITF 07-3”). EITF 07-3 clarifies the accounting for nonrefundable advance payments for goods or services that will be used or rendered for research and development activities. EITF 07-3 states that such payments should be capitalized and recognized as an expense as the goods are delivered or the related services are performed. If an entity does not expect the goods to be delivered or the services rendered, the capitalized advance payment should be charged to expense. The Company adopted EITF 07-3 on January 1, 2008. The adoption of EITF 07-3 did not have a material effect on the Company’s financial statements for the year ended December 31, 2008.

**(3) Marketable Securities**

The Company’s short-term available-for-sale investments at market value consisted of the following at December 31, 2008 and 2007:

	<b>December 31, 2008</b>			
	<u>Cost</u>	<u>Gross Unrealized Losses</u>	<u>Gross Unrealized Gains</u>	<u>Estimated Fair Value</u>
		(In thousands)		
Corporate bonds due in one year or less	\$10,477	\$ 44	\$ 8	\$ 10,441
	<b>December 31, 2007</b>			
	<u>Cost</u>	<u>Gross Unrealized Losses</u>	<u>Gross Unrealized Gains</u>	<u>Estimated Fair Value</u>
		(In thousands)		
Corporate bonds due in one year or less	\$ 1,653	\$ —	\$ —	\$ 1,653
Certificates of deposit due in one year or less	2,801	—	—	2,801
Government bonds due in one year or less	6,693	—	8	6,701
Total	<u>\$11,147</u>	<u>\$ —</u>	<u>\$ 8</u>	<u>\$ 11,155</u>

See Note 2 (g).

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

**(4) Property and Equipment**

At December 31, 2008 and 2007, net property and equipment at cost consists of the following:

	December 31,	
	2008	2007
	(In thousands)	
Leasehold improvements	\$ 514	\$ 430
Laboratory equipment and other	2,694	2,585
Total property and equipment, at cost	3,208	3,015
Less: Accumulated depreciation and amortization	1,384	1,051
Property and equipment, net	<u>\$ 1,824</u>	<u>\$ 1,964</u>

As of December 31, 2008 and 2007, laboratory equipment and other included approximately \$79,000 and \$98,000, respectively, of office equipment financed under capital leases with accumulated depreciation of approximately \$25,000 and \$19,000, respectively.

Depreciation expense, which includes amortization of assets recorded under capital leases, was approximately \$530,000, \$364,000, and \$247,000 in 2008, 2007 and 2006, respectively.

The Company vacated its previous facility in the second quarter of 2007. Consequently as of December 31, 2007, the Company wrote off fully amortized leasehold improvements that had a cost of approximately \$445,000. The Company also wrote off unused furniture, and obsolete software, computers and other equipment that had an aggregate cost of approximately \$874,000 resulting in a loss of approximately \$6,000. In 2008 and 2006, the Company wrote off unused property and equipment that had a gross cost of approximately \$200,000 and \$185,000, respectively. The write-off of property and equipment resulted in a loss of approximately \$2,000 for the year ended December 31, 2008 and a negligible loss for the year ended December 31, 2006.

**(5) Accrued Expenses**

At December 31, 2008 and 2007, accrued expenses consist of the following:

	December 31,	
	2008	2007
	(In thousands)	
Payroll and related costs	\$ 73	\$ 446
Clinical and nonclinical trial expenses	705	598
Professional and consulting fees	230	415
Other	191	286
	<u>\$ 1,199</u>	<u>\$ 1,745</u>

**(6) Debt**

*(a) Notes 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.

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

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. The Note has been 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.

**(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, 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
<b>Short-term investments at December 31, 2007</b>			
Aggregate fair value of investments with unrealized losses (includes accrued interest of \$97)	\$ 2,000	\$ —	\$ 2,000
Aggregate amount of unrealized losses	\$ —	\$ —	\$ —

There were no long-term investments at December 31, 2008 and 2007.

The Company holds five investments which have an aggregate market value of \$5,269,000 and a gross unrealized loss aggregating \$44,000 at December 31, 2008. There are no related realized losses recorded in the Statement of Operations during the year ended December 31, 2008. Some of the factors reviewed in making the determination not to recognize any losses as of December 31, 2008 are presented below.

All of these investments are investment grade corporate bonds of which two have an aggregate amortized cost of \$2,008,000 and represent \$37,000 or 84% of the unrealized loss. The Company believes that each of these two issuers have strong positions within their respective segments of the financial services industry.

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

The unrealized losses on investments at December 31, 2008, shown in the above table, were primarily due to deterioration, volatility and illiquidity in the broader credit markets that resulted in widening of credit spreads over risk free rates well beyond historical norms, rather than any significant credit downgrades on these securities. Because the Company has the ability and intent to hold these securities until a recovery of fair value to amortized cost, which may be their maturity during 2009, the Company currently believes it is probable that it will collect all amounts due according to their respective contractual terms. Therefore, there were no declines in value that were judged to be other-than-temporary as of 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. In addition, beginning on May 31, 2007, if specified conditions are satisfied, Novartis may expand the collaboration to include additional human disease areas, other than oncology and infectious diseases. Under the terms of the agreements, upon execution of the agreements, Novartis paid the Company a \$4.0 million upfront license fee; Novartis agreed to fund substantially all research activities during the research collaboration phase; if Novartis elects to exercise its option to develop and commercialize licensed TLR9 agonists in the initial collaboration disease areas, Novartis is potentially obligated to pay the Company up to \$132.0 million based on the achievement of clinical development, regulatory approval, and annual net sales milestones; Novartis is potentially obligated to pay the Company additional milestone payments if Novartis elects to expand the collaboration to include additional disease areas and then develops and commercializes licensed TLR9 agonists in the additional disease areas based on the achievement of clinical development and regulatory approval milestones; and Novartis is also obligated to pay the Company royalties on net sales of all products, if any, commercialized by Novartis, its affiliates and sublicensees. Novartis' license rights under the agreements to products that it elects to develop and commercialize are worldwide, exclusive rights.

The Company and Novartis agreed that the term of the research and collaboration phase would be two years commencing in May 2005. The Company initially was recognizing the \$4.0 million upfront payment as revenue over the two-year term of the research collaboration. In February 2007, the Company received notice that Novartis had elected to extend the research collaboration by an additional year until May 2008, and for such extension Novartis paid the Company an additional \$1.0 million. In connection with this amendment, the Company extended the time period over which it is amortizing the upfront payment and the \$1.0 million extension payment. In 2008, the research collaboration was extended until December 31, 2008. The Company amortized 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.

*(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 and incorporating both Merck & Co. and Idera chemistry for use in vaccines in the defined fields, which may be extended by Merck & Co. for two

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

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 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 could be extended. 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.

*(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 agreement 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 on-going IMO-2055 clinical trials, which will continue to be conducted by Idera; 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 royalties on net sales of products containing our TLR9 agonists that are marketed.

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.

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

*(d) Other License Agreements*

The Company is a party to four collaboration and license agreements involving the use of its antisense technology and specified indications. These agreements include a license agreement with Isis Pharmaceuticals, Inc., or Isis, involving intellectual property for antisense chemistry and delivery. Under the agreement with Isis, the Company granted Isis a license, with the right to sublicense, to its antisense chemistry and delivery patents and patent applications; and the Company retained the right to use these patents and applications in its own drug discovery and development efforts and in collaborations with third parties. Isis paid the Company an initial licensing fee and is required to pay the Company a portion of specified sublicense income it receives from some types of sublicenses of the Company's patents and patent applications. Also under the agreement, the Company licensed from Isis specified antisense patents and patent applications, principally Isis' suite of RNase H patents and patent applications. The Company also paid an initial licensing fee for this license and is obligated to pay Isis a maintenance fee and royalties. The Company has the right to use these patents and patent applications in its drug discovery and development efforts and in some types of third-party collaborations. The licenses granted under the Isis agreement terminate upon the last to expire of the patents and patent applications licensed under the agreement. The Company may terminate at any time the sublicense by Isis to it of the patents and patent applications.

The Company is also a party to three other license agreements involving the license of its antisense patents and patent applications for specific gene targets under which it typically is entitled to receive license fees, sublicensing income, research payments, payments upon achievement of developmental milestones, and royalties on product sales. These agreements typically expire upon the later of the last to expire of the licensed patents or a specified number of years after the first commercial sale of a licensed product. These agreements may be terminated by either party for a material breach, and collaborators may terminate these agreements at any time for convenience, with written notice.

The Company is also 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's principal in-license is with University of Massachusetts Medical Center for chemistry and for certain gene targets. Under all of these in-licenses, the Company is obligated to pay royalties on its net sales of products or processes covered by a valid claim of a licensed patent or patent application. In certain cases, the Company is required to pay a specified percentage of any sublicense income, and all of these licenses impose various commercialization, sublicensing, insurance, and other obligations on the Company, and its failure to comply with these requirements could result in termination of the licenses. Additionally, as part of a 2003 interference resolution for one of the licensed patents, a settlement was made enabling the Company to receive a percentage of the royalty amounts the National Institutes of Health receives for the sale of a product that is covered by such patent.

**(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

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

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.

The Company repurchased or received documentation of the transfer of 348,235 Put Shares. As of December 31, 2008, 102,770 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 748,679 Put Shares have terminated.

*(b) Warrants*

The Company has the following warrants outstanding and exercisable for the purchase of common stock at December 31, 2008:

Expiration Date	Shares	Weighted Exercise Price per Share
April 20, 2009	194,818	\$ 9.12
September 24, 2011	2,466,263	5.42
	<u>2,661,081</u>	
Weighted average exercise price per share		\$ 5.69

The warrants that expire in 2011 are described in Note 16.

*(c) Stock Options*

The 1995 Stock Option Plan provided for the grant of incentive stock options and nonqualified stock options. No additional options are being granted under the 1995 Stock Option Plan. As of December 31, 2008, options to purchase a total of 27,992 shares of common stock remained outstanding under the 1995 Stock Option Plan.

The 1995 Director Stock Option Plan provided for the grant of stock options. No additional options are being granted under the Director Plan. As of December 31, 2008, options to purchase a total of 69,464 shares of common stock remained outstanding under the Director Plan.

The 1997 Stock Incentive Plan provided for the grant of incentive stock options and nonqualified stock options. Options granted under this plan generally vest over three to five years, and expire no later than ten years from the date of grant. No additional options are being granted under the 1997 Stock Incentive Plan. As of December 31, 2008, options to purchase a total of 879,682 shares of common stock remained outstanding under the 1997 Stock Incentive Plan.

The 2005 Stock Incentive Plan provided for the grant of 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. No options may be granted under the 2005 Stock Incentive Plan after June 3, 2008. As of December 31, 2008, options to purchase a total of 1,537,103 shares of common stock remained outstanding under the 2005 Stock Incentive Plan.

Under the 2008 Stock Incentive Plan, the Company may grant of 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

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

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 in the case of incentive stock options 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, 2008, options to purchase a total of 690,100 shares of common stock remained outstanding under the 2008 Stock Incentive Plan. As of December 31, 2008, 3,009,182 shares of common stock remain available for grant under the 2008 Stock Incentive Plan.

The Company's 1995 Stock Option Plan, the 1995 Employee Stock Purchase Plan, the 1995 Director Stock Option Plan, the 1997 Stock Incentive Plan, the 2005 Stock Incentive Plan and the 2008 Stock Incentive Plan have been approved by the Company's stockholders. In 2001, the Company also granted options to purchase shares of Common Stock pursuant to agreements that were not approved by stockholders.

The following table summarizes information related to the outstanding and exercisable options during 2008 (in thousands, except per share amounts and years):

	Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2007	2,750	\$ 5.77		
Granted	1,336	11.34		
Exercised	(359)	5.30		
Forfeited	(180)	5.59		
Expired	(1)	11.30		
Outstanding at December 31, 2008	<u>3,546</u>	<u>\$ 7.92</u>	6.89	\$ 4,678
Exercisable at December 31, 2008	<u>2,008</u>	<u>\$ 6.30</u>	5.13	\$ 4,020
Total exercisable or expected to vest	<u>3,520</u>	<u>\$ 7.91</u>	6.87	\$ 4,667

*(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.

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

Offering periods are three months in duration and commence on March 1, June 1, September 1, and December 1. In 2008, 2007, and 2006, the Company issued 11,926, 10,364 and 18,241 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, 2008 and 2007, 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 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, 2008 or 2007.

*(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 has 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 2008, 2007 and 2006, rent expense, including real estate taxes and net of sublease income that ended in January 2007, was \$1,441,000, \$1,221,000 and \$329,000, respectively. As part of the lease, the Company was required to restrict approximately \$619,000 of cash for a security deposit. The lease is classified as an operating lease. Total payments over the seven-

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

year term of the lease are approximately \$9.0 million. Future minimum commitments as of December 31, 2008 under the Company's lease agreement are approximately:

<u>December 31,</u>	<u>Operating Leases (In thousands)</u>
2009	1,219
2010	1,261
2011	1,306
2012	1,351
2013	1,398
2014	591
	<u>\$ 7,126</u>

*(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 2011, with its president, chief executive officer and chief scientific officer. As of December 31, 2008, future minimum commitments under this agreement are approximately \$510,000, \$510,000 and \$409,000 for the years ended December 31, 2009, 2010, and 2011, respectively.

*(d) Related-Party Agreements with Affiliates of Stockholders and Directors*

In connection with the 2006 common stock purchase commitment described in Note 16, the Company paid one of the Company's directors a commission of \$487,500, which represented 5% of the amount available to the Company under the purchase agreement.

The Company paid other directors consulting fees of approximately \$101,000 and \$10,000 in 2008 and 2006, respectively. There were no consulting fees paid to directors during 2007.

**(11) Income Taxes**

Subject to the limitations described below, at December 31, 2008, the Company had cumulative net operating loss carryforwards of approximately \$275.6 million and \$43.4 million available to reduce federal and state taxable income which expire through 2028 and 2013, respectively. In addition, the Company has cumulative federal and state tax credit carryforwards of \$5.5 million and \$4.3 million, respectively, available to reduce federal and state income taxes which expire through 2028 and 2023, respectively. The net operating loss carryforwards include approximately \$1.9 million of deductions related to the exercise of stock options subsequent to the adoption of SFAS No. 123R. This amount represents an excess tax benefit as defined under SFAS No. 123R and has not been included in the gross deferred tax asset reflected for net operating losses.

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, 2008, have resulted in ownership changes in excess of 50%, as

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

defined under the Act and that may significantly limit the Company's ability to utilize its net operating loss and tax credit carryforwards. The Company has not prepared an analysis to determine the effect of the ownership change limitation on its ability to utilize its net operating loss and tax credit carryforwards. Ownership changes in future periods may place additional limits on the Company's ability to utilize net operating loss and tax credit carryforwards.

As of December 31, 2008 and 2007, the components of the deferred tax assets are approximately as follows:

	2008	2007
	(In thousands)	
Operating loss carryforwards	\$ 95,680	\$ 97,923
Tax credit carryforwards	8,361	8,417
Other	5,624	7,268
	109,665	113,608
Valuation allowance	(109,665)	(113,608)
	<u>\$ —</u>	<u>\$ —</u>

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 \$3.9 million which is attributable to a decrease in deferred tax assets associated with the expiration of net operating loss carryforwards and collaboration revenue recognized for financial statement purposes in the current year which had been recognized for tax purposes during prior years.

For the years ended December 31, 2008, 2007 and 2006, the primary 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 increase in the valuation allowance.

The Company adopted the FASB's Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109* ("FIN 48"), effective January 1, 2007. FIN 48 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 FIN 48 did not have any effect on the Company's financial position or results of operations.

The Company has not, as yet, conducted a study of its research and development credit carryforwards. This study may 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 FIN 48. 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 2003, except to the extent that it utilizes net operating losses or tax credit carryforwards that originated before 2003. 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.

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

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

\$50,000 as a result of the payment from Merck KGaA generating income that the Company believed would be subject to the alternative minimum tax, or AMT. The Company subsequently reversed the \$50,000 recorded as income tax expense as the Company no longer expects to have income subject to AMT. The Company did not have income subject to AMT in 2007. There was \$45,000 in alternative minimum tax expense for 2006.

**(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 \$78,000, \$118,000 and \$97,000 of 401(k) benefits were charged to continuing operations during 2008, 2007 and 2006, respectively.

**(13) Income Per Share**

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

	(In thousands, except per share amounts)
Numerator for basic and dilutive net income per share:	
Net income	\$ 1,509
Denominator for basic income per share:	
Weighted average common shares outstanding	22,655
Effect of restricted stock grant	52
Effect of dilutive common stock options and warrants	2,624
Denominator for diluted income per share	25,331
Basic income per share	\$ 0.07
Diluted income per share	\$ 0.06

For the year ended December 31, 2008, 1,117,000 shares 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 2008.

Basic and diluted net loss per common share is computed using the weighted average number of shares of common stock outstanding during the period. For the years ended December 31, 2007 and 2006, diluted net loss per share of common stock is the same as basic net loss per share of common stock, as the effects of the Company's potential common stock equivalents are antidilutive. Total antidilutive securities were approximately 7,210,000 and 8,138,000 at December 31, 2007 and 2006, respectively, and consist of stock options, warrants and convertible preferred stock. Antidilutive securities for the year ended December 31, 2006 also includes convertible debt instruments on an as-converted basis. Net loss applicable to common stockholders is the same as net loss for years ended December 31, 2007 and 2006.

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

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

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

	Years Ended December 31,		
	2008	2007	2006
	(In thousands)		
Supplemental disclosure of cash flow information:			
Cash paid for interest	\$ 92	\$ 149	\$ 176
Cash paid for income taxes	\$ 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	\$ 22	\$ 44	\$ 27
Equipment acquired under capital lease	\$ —	\$ 78	\$ —

**(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.

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

**(16) Equity Offerings**

In March 2006, the Company raised approximately \$9.8 million in gross proceeds from a private placement to institutional investors. In the private placement, the Company sold for a purchase price of \$3.52 per share approximately 2,770,000 shares of common stock and warrants to purchase approximately 2,077,000 shares of common stock. The warrants to purchase common stock have an exercise price of \$5.20 per share, are fully exercisable, and will expire if not exercised on or prior to September 24, 2011. The warrants may be exercised by cash payment only. After March 24, 2010, the Company may redeem the warrants for \$0.08 per warrant share following notice to the warrant holders if the volume weighted average of the closing sales price of the common stock exceeds 300% of the warrant exercise price for the 15-day period preceding the notice. The Company may exercise its right to redeem the warrants by providing 20 days' prior written notice to the holders of the warrants. The net proceeds to the Company from the offering, excluding the proceeds of any future exercise of the warrants, were approximately \$8.9 million. The agent fees and other costs directly related to securing the commitment amounted to approximately \$0.9 million. The Company has filed a registration statement covering the resale of the common stock and the common stock issuable upon exercise of the warrants, which has been declared effective.

In March 2006, the Company secured a purchase commitment from an investor to purchase from the Company up to \$9.8 million of the Company's common stock during the period from June 24, 2006 through December 31, 2006 in up to three drawdowns made by the Company at the Company's discretion. Prior to December 31, 2006, the Company drew down the full \$9.8 million through the sale of approximately 1,904,000 shares of common stock at a price of \$5.12 per share resulting in net proceeds to the Company, excluding the proceeds of any future exercise of the warrants, described below, of approximately \$8.9 million. The agent fees and other costs directly related to securing the commitment amounted to approximately \$0.9 million. As part of the arrangement, the Company issued warrants to the investor to purchase approximately 762,000 shares of common stock at an exercise price of \$5.92 per share. The warrants are exercisable by cash payment only. The warrants are exercisable at any time on or prior to September 24, 2011. On or after March 24, 2010, Idera may redeem the warrants for \$0.08 per warrant share following notice to the warrant holders if the closing sales price of the common stock exceeds 250% of the warrant exercise price for 15 consecutive trading days prior to the notice. The Company may exercise its right to redeem the warrants by providing at least 30 days' prior written notice to the holders of the warrants.

**(17) 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

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

Company received approximately \$503,000 in proceeds from the exercise of the May 2005 warrant to purchase 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.

**(18) Subsequent Events**

In February 2009, the Company achieved a milestone under its agreement with Merck KGaA upon the dosing of the first patient in a clinical trial of IMO-2055 in combination with Erbitux and Camptosar in patients with colorectal cancer. Under the terms of the agreement, the Company is entitled to recognize and receive a payment of €3.0 million (approximately \$3.8 million) from Merck KGaA. In February 2009, the Company amended its license agreement with Merck KGaA so that Idera could initiate and conduct on behalf of Merck KGaA additional clinical trials of IMO-2055, until such time as Merck has filed an IND application with the FDA and assumes sponsorship of these trials. Under the amendment, Merck KGaA has agreed to reimburse the Company for costs associated with any additional trials that the Company initiates and conducts.

**Exhibit Index**

Exhibit Number	Description	Filed with this Form 10-K	Incorporated by Reference		
			Form or Schedule	Filing Date with SEC	SEC File Number
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 the Company 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 the Company 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 the Company 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††	1995 Stock Option Plan.		S-1	November 6, 1995	33-99024
10.4††	1995 Director Stock Option Plan.		8-K	June 10, 2008	001-31918
10.5††	1995 Employee Stock Purchase Plan, as amended.		8-K	June 10, 2008	001-31918
10.6††	Employment Agreement dated October 19, 2005 between Idera Pharmaceuticals, Inc. and Dr. Sudhir Agrawal.		10-Q	November 9, 2005	001-31918
10.7††	Amendment, dated December 17, 2008 to Employment Agreement by and between the Idera Pharmaceuticals, Inc. and Dr. Sudhir Agrawal dated October 19, 2005.		8-K	December 18, 2008	001-31918
10.8††	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
10.9††	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
10.10††	Non-Employee Director Compensation Program Effective January 1, 2008.		10-K	March 11, 2008	001-31918

[Table of Contents](#)

Exhibit Number	Description	Filed with this Form 10-K	Incorporated by Reference		
			Form or Schedule	Filing Date with SEC	SEC File Number
10.11††	Amended and Restated 1997 Stock Incentive Plan.		10-Q	May 15, 2001	000-27352
10.12††	Non-Employee Director Nonstatutory Stock Option Agreement Granted under 1997 Stock Incentive Plan.		10-K	March 25, 2005	001-31918
10.13††	Form of Incentive Stock Option Agreement Granted Under the 2005 Stock Incentive Plan.		8-K	June 21, 2005	001-31918
10.14††	Form of Nonstatutory Stock Option Agreement Granted Under the 2005 Stock Incentive Plan.		8-K	June 21, 2005	001-31918
10.15††	Form of Restricted Stock Agreement Under the 2005 Stock Incentive Plan.		10-Q	August 1, 2007	001-31918
10.16††	Form of Incentive Stock Option Agreement Granted Under the 2008 Stock Incentive Plan.		8-K	June 10, 2008	001-31918
10.17††	Form of Nonstatutory Stock Option Agreement Granted Under the 2008 Stock Incentive Plan.		8-K	June 10, 2008	001-31918
10.18††	Form of Nonstatutory Stock Option Agreement (Non-Employee Directors) Granted Under the 2008 Stock Incentive Plan.		8-K	June 10, 2008	001-31918
10.19††	Form of Restricted Stock Agreement Under the 2008 Stock Incentive Plan.		8-K	June 10, 2008	001-31918
10.20††	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
10.21†	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
10.22††	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
10.23††	License Agreement dated February 21, 1990 and restated as of September 8, 1993 between Idera Pharmaceuticals, Inc. and University of Massachusetts Medical Center.		S-1	November 6, 1995	33-99024
10.24†	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

[Table of Contents](#)

Exhibit Number	Description	Filed with this Form 10-K	Incorporated by Reference		
			Form or Schedule	Filing Date with SEC	SEC File Number
10.25†	Collaboration and License Agreement by and between Isis Pharmaceuticals, Inc., and Idera Pharmaceuticals, Inc., dated May 24, 2001.		10-Q	August 20, 2001	000-27352
10.26	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
10.27	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
10.28	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
10.29	Registration Rights Agreement, dated as of August 28, 2003 by and among Idera Pharmaceuticals, Inc., the Purchasers and the Agents.		S-2	October 10, 2003	333-109630
10.30	Form of Common Stock Purchase Warrant issued to purchasers of units in a private placement on August 28, 2003 and August 29, 2003.		S-2	October 10, 2003	333-109630
10.31	Form of Common Stock Purchase Warrant issued to selected dealers and placement agents on August 28, 2003 in connection with a private placement.		S-2	October 10, 2003	333-109630
10.32	Registration Rights Agreement, dated August 27, 2004 by and among Idera Pharmaceuticals, Inc., Pillar Investment Limited and Purchasers.		10-Q	November 12, 2004	001-31918
10.33	Form of Warrants issued to investors and the placement agent in connection with Idera Pharmaceuticals, Inc. August 27, 2004 financing.		10-Q	November 12, 2004	001-31918
10.34†	Research Collaboration and Option Agreement by and between Idera Pharmaceuticals, Inc. and Novartis International Pharmaceutical Ltd.		10-Q	August 9, 2005	001-31918
10.35†	License, Development and Commercialization Agreement by and between Idera Pharmaceuticals, Inc and Novartis International Pharmaceutical Ltd.		10-Q	August 9, 2005	001-31918
10.36	Engagement letter, dated May 20, 2005, by and among Idera Pharmaceuticals, Inc. and Pillar Investment Limited.		10-Q	August 9, 2005	001-31918

[Table of Contents](#)

Exhibit Number	Description	Filed with this Form 10-K	Incorporated by Reference		
			Form or Schedule	Filing Date with SEC	SEC File Number
10.37	Consulting Agreement dated as of January 1, 2008 between Idera Pharmaceuticals, Inc. and Karr Pharma Consulting, LLC.		10-K	March 11, 2008	001-31918
10.38	Amendment dated December 16, 2008 to Consulting Agreement dated as of January 1, 2008 between Idera Pharmaceuticals, Inc. and Karr Pharma Consulting, LLC.	X			
10.39	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
10.40	Common Stock Purchase Warrant issued to Pillar Investment Limited in connection with the May 20, 2005 Financing.		10-Q	August 9, 2005	001-31918
10.41	Common Stock Purchase Agreement, dated March 24, 2006, by and among the Company and the Investors named therein.		8-K	March 29, 2006	001-31918
10.42	Registration Rights Agreement, dated March 24, 2006, by and among the Company and the Investors named therein.		8-K	March 29, 2006	001-31918
10.43	Amendment No. 1 to the Common Stock Purchase Agreement, dated March 24, 2006, by and among the Company and the Investors named therein.		10-Q	August 14, 2006	001-31918
10.44	Form of Warrant issued to Investors in the Company's March 24, 2006 Private Financing.		8-K	March 29, 2006	001-31918
10.45	Common Stock Purchase Agreement, dated March 24, 2006, by and between the Company and Biotech Shares Ltd.		8-K	March 29, 2006	001-31918
10.46	Amendment No. 1 to the Common Stock Purchase Agreement, dated March 24, 2006, by and among the Company and Biotech Shares Ltd.		10-Q	November 13, 2006	001-31918
10.47	Engagement Letter, dated March 24, 2006, between the Company and Youssef El Zein.		8-K	March 29, 2006	001-31918
10.48	Registration Rights Agreement, dated March 24, 2006, by and among the Company, Biotech Shares Ltd. and Youssef El Zein.		8-K	March 29, 2006	001-31918
10.49	Warrant issued to Biotech Shares Ltd. on March 24, 2006.		8-K	March 29, 2006	001-31918

---

[Table of Contents](#)

Exhibit Number	Description	Filed with this Form 10-K	Incorporated by Reference		
			Form or Schedule	Filing Date with SEC	SEC File Number
10.50†	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
10.51	Amendment No. 1 to the Registration Rights Agreement dated March 24, 2006, by and among the Company and Biotech Shares Ltd.		10-Q	August 14, 2006	001-31918
10.52	Promissory Note dated June 12, 2007 made by Idera Pharmaceuticals, Inc. in favor of General Electric Capital Corporation.		10-Q	August 1, 2007	001-31918
10.53	Master Security Agreement dated June 12, 2007 by and between Idera Pharmaceuticals, Inc. and General Electric Capital Corporation.		10-Q	August 1, 2007	001-31918
10.54†	License Agreement by and between Merck KGaA and Idera Pharmaceuticals, Inc., dated December 18, 2007.		10-K	March 11, 2008	001-31918
10.55*	Amendment dated February 12, 2009 to the License Agreement by and between Merck KGaA and Idera Pharmaceuticals, Inc., dated December 18, 2007.	X			
23.1	Consent of Independent Registered Public Accounting Firm.	X			
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002.	X			
31.2	Certification of Chief Financial Officer 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 requested as to certain portions, which portions are omitted and filed separately with the Commission.

† 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.

**AMENDMENT TO THE CONSULTING SERVICES AGREEMENT**

This Amendment, effective the 16<sup>th</sup> day of December, 2008, (“Amendment Date”) is by and between **Idera Pharmaceuticals, Inc.**, a Delaware corporation, having an place of business at 167 Sidney Street, Cambridge, Massachusetts 02139 (hereinafter referred to as “Idera”) and **Karr Pharma Consulting, LLC**, having a place of business at 707 Dominion Drive, St. Louis, Missouri 63131 (hereinafter referred to as the “Consultant”). Idera and Consultant may be referred to herein individually as a “Party” and collectively as the “Parties.”

**Background**

The Parties entered into a Consulting Services Agreement (“Agreement”), dated January 1, 2008 (“Effective Date”), which set forth certain terms and conditions for the Consultant to perform services for Idera.

The Parties now desire to amend the Agreement to extend the term through December 31, 2009.

Now, Therefore, the Parties hereby agree as follows:

Section 2 of the Agreement shall be amended and restated in its entirety as follows:

**TERM.** This Agreement shall commence on the Effective Date and shall continue until December 31, 2009 (such period, as it may be extended, being referred to as the “Consultation Period”), unless sooner terminated in accordance with the provisions of Section 4.

All other terms and conditions of the Agreement shall remain in full force and effect.

IN WITNESS WHEREOF, the Parties have executed this Amendment as of the Amendment Date.

**Idera Pharmaceuticals, Inc.**

By: /s/ Louis J. Arcudi, III  
Louis J. Arcudi, III  
Chief Financial Officer

Date: 12/16/2008

**Karr Pharma Consulting, LLC**

By: /s/ Robert W. Karr, M.D.  
Robert W. Karr, M.D.

Date: 12/16/2008

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

### Amendment To The License Agreement

This Amendment, effective the 12th day of February, 2009, (“**Amendment Date**”) is by and between Idera Pharmaceuticals, Inc., having a place of business located at 167 Sidney Street, Cambridge, Massachusetts 02139 (“**Idera**”) and Merck KGaA, a general partnership limited by shares organized under German law having a place of business at Frankfurter Strasse 250, 64293 Darmstadt, Germany (“**Merck**”). Idera and Merck may be referred to collectively as “Parties.”

### Background

The Parties entered into a License Agreement dated 18 December 2007 (“**License Agreement**”), which sets forth certain terms and conditions for the Parties to research, develop and commercialize immune modulatory oligonucleotides in the field of cancer.

The Parties now desire to amend the License Agreement to allow Idera to continue to act as the sponsor (as such term is defined in 21 CFR § 312.3(b), hereinafter “**Sponsor**”) of certain clinical trials until such time as Merck has filed an Investigational New Drug application with the US Food and Drug Administration and assumes the Sponsor role under the Merck IND.

Now, Therefore, the Parties hereby agree as follows:

1. Section 1.17, definition of “Development Costs” is hereby amended and restated in its entirety as follows:

“**Development Costs**” means those Out-of-Pocket Expenses incurred by Licensor after the Effective Date that are directly and solely attributable to the achievement of work or activities performed by or on behalf of Licensor after the Effective Date toward the completion of the On-Going Trials or the Future Trials.

2. Section 3.4, of the License Agreement, Licensor Support in the Development, is hereby amended and restated in its entirety as follows:

3.4(a). **Licensor Support in the Development.** For a period of [\*\*] starting from Effective Date, Licensor shall make its employees that are knowledgeable on the Compound or Follow-On Compound, its properties and functions, reasonably available to Merck, at Licensor’s facilities, for scientific and technical explanations, advice and support, that may reasonably be required by Merck, relating to the Development and registration of the Compound, Follow-On Compound and the Licensed Products (the “**Development Support**”). The Development Support shall be provided by Licensor [\*\*] during such first [\*\*] following the Effective Date. Thereafter, during the remaining [\*\*] period, Merck shall reimburse Licensor for Licensor’s reasonable Out-of-Pocket Expenses incurred in providing the Development Support should Merck require any of such Development Support, subject however to Licensor providing Merck with documented evidence of such Out-of-Pocket Expenses having been incurred.

3.4(b). **Licensor Sponsorship and Conduct of Clinical Trials.** Notwithstanding Section 2.3 and 3.4(a), during the Interim Period Licensor agrees to remain the Sponsor for the On-Going Trials and for additional Clinical Trials that the Parties agree to conduct during the Interim Period, including the study in [\*\*] (“**Future Trials**” and together with the On-Going Trials, collectively, the “TLR9 Agonist Trials”). For purposes of this Agreement, the “Interim Period” means that period of time commencing on the Effective Date and ending on the date that is the earlier of (i) the date on which the FDA has approved the IND submitted by Merck for conducting clinical trials with Licensor’s TLR9 agonists (the “**Merck TLR9 Agonists IND**”) and Merck has assumed the role of Sponsor for all on-going TLR9 Agonist Trials or (b) the date that is [\*\*] from the Effective Date. The following provisions shall apply during the Interim Period in connection with the conduct of the TLR9 Agonist Trials:

- (1) Such trials shall be conducted under Licensor’s IND Application Number[\*\*] or IND Application Number [\*\*].
- (2) Licensor’s acts shall be in compliance with Section 3.2.
- (3) The Parties shall establish an agreement for each TLR9 Agonist Trial that sets forth each Party’s responsibilities (the “**Charter Agreements**”).
- (4) The Charter Agreements shall, at a minimum, identify a process for developing and executing the protocol for each TLR9 Agonist Trial and set forth a trial budget to be paid by Merck, which shall include after [\*\*] the reimbursement by Merck of Licensor’s internal costs, up to an agreed upon limit and at an agreed upon rate to be set forth in the budget attached to the respective Charter Agreement and pre-approved Development Costs in conducting such trial (each a “**Trial Budget**”).
- (5) Merck shall have responsibility for determining if any Future Trial is to be conducted and for defining objectives of any Future Trial.
- (6) Merck shall seek Licensor’s input on each Future Trial.
- (7) If requested by Merck during the Interim Period, Licensor agrees to initiate and conduct the [\*\*] Trial during the Interim Period, subject to the terms of a mutually agreed Charter Agreement, unless Licensor, in its reasonable discretion, determines that it is unable to conduct such trial, wherein such determination takes into account [\*\*] under the relevant Charter Agreement.
- (8) For each Future Trial [\*\*] that Merck desires to initiate during the Interim Period, Licensor agrees to initiate and conduct such Future Trial during the Interim Period, subject to the terms of a mutually agreed Charter Agreement, unless Licensor, in its sole discretion, determines that it is unable to conduct such trial. Such inability determination shall take into [\*\*] under the relevant Charter Agreement.
- (9) Licensor shall have the right to take, at its sole discretion after appropriate discussions with Merck under the Charter Agreements, any actions it reasonably deems necessary or desirable to fulfill the regulatory requirements appropriate to the role of Sponsor for any or all TLR9 Agonist Trials.
- (10) For the avoidance of doubt, if the Initiation of a Future Trial by Idera would qualify as a milestone payment triggering event as set forth in Section 5.2 if

such Initiation had been undertaken by Merck, such milestone shall be considered achieved as if Merck achieved such milestone and all payments resulting therefrom shall be due and payable by Merck to Idera according to the Agreement.

- (11) Notwithstanding Section 3.4(b)(10), the Parties agree that the Initiation of the [\*\*] Trial shall in no event be considered [\*\*].
- (12) Licensor's acts pursuant to the provisions of this Section 3.4(b) shall not be considered a breach of Section 2.6 or Section 3.1.
- (13) Merck's acts pursuant to the provisions of this Section 3.4(b), as well as the fact that Merck [\*\*], shall not be considered a breach of Section 3.2 or Section 3.9.
- (14) Licensor has entered into a contract with [\*\*] pursuant to which [\*\*] is to perform certain labeling, storage, packing and distribution activities related to [\*\*] on behalf of Licensor. During the Interim Period and in accordance with Merck's direction, Licensor shall manage the labeling, packing and distribution of [\*\*] vials of [\*\*] via [\*\*] for purposes of (i) completion of transfer of the manufacturing technology as provided for under this License Agreement, (ii) the On-Going Trials and (iii) any Future Trials. Licensor shall not be responsible for manufacturing any amounts of [\*\*] in addition to the [\*\*] vials referenced in this clause (14). To the extent that Licensor follows the direction given by Merck pursuant to this clause (14), Merck shall be accountable for the allocation of such vials to the transfer of the manufacturing technology activities, the On-Going Trials and any Future Trials
- (15) With respect to each TLR9 Agonist Trial, Licensor shall own the corresponding clinical data generated by that Trial (the "Clinical Data") until such time as Merck shall [\*\*]. Merck shall have a fully paid, royalty free, exclusive license to use, disclose and copy the Clinical Data related to such Trial to bring about the purposes of this License Agreement, the Charter Agreements and the filing of the Merck TLR9 Agonists IND. Licensor shall retain the right to use, disclose and copy (i) any and all Clinical Data during the Interim Period as necessary to comply with applicable laws, rules and regulations and to publish in accordance with Section 7.2 of the License Agreement, (ii) any safety data in connection with contractual pharmacovigilance obligations to third parties and (iii) the final study report for [\*\*] to the extent necessary to comply with [\*\*]. In connection with the foregoing and to the fullest extent permitted by law, Licensor shall authorize any contract research organization, data management company or central laboratory providing services in respect of a TLR9 Agonist Trial to concurrently disclose the related Clinical Data to Merck or Merck's designee. In respect of Clinical Data for a TLR9 Agonist Trial generated by a Third-Party vendor other than a contracts research organization, data management company or central laboratory, Licensor shall promptly and timely disclose Clinical Data to Merck after receipt thereof from such Third-Party vendor. Without additional action or payment of an additional fee, ownership of the Clinical Data will transfer from

Licensors to Merck at the end of the Interim Period; provided, that Licensor shall have a fully paid, royalty free, non-exclusive license to use and disclose (i) the Clinical Data for purposes of any required regulatory filings in connection with a TLR9 Agonist Trial or to respond to any regulatory inquiries related to the period when Licensor was Sponsor of such Trial and (ii) any safety data that are generated from a TLR9 Agonist Trial for Licensor's and its collaborators' and their affiliates' regulatory purposes.

- (16) Licensor agrees that during such time that Licensor is owner of any Clinical Data, such ownership rights shall be subject to and to the extent applicable, limited by, the terms of this License Agreement, including Section 7.2(c).
- (17) Strategic Development Committee.
- (i) The Parties shall establish a committee for the purpose of reviewing and exchanging information regarding the general direction and progress of the TLR9 Agonist Trials during the Interim Period (the "Strategic Development Committee" or "SDC"). Each Party shall designate two (2) individuals to be its authorized representatives on the Strategic Development Committee (each a "SDC Representative"). Merck shall also appoint one of the SDC Representatives it has designated as the chair of the Strategic Development Committee (the "SDC Chair"). The initial SDC Representatives and chairperson are set forth on Schedule 3.4(b). Each Party may change its SDC Representatives, or Merck may change its designee for the SDC Chair, as the case may be, from time to time, effective upon notice to the other Party of such change. Additional representatives or consultants may from time to time, by mutual consent of the Parties, be invited to attend SDC meetings. Except as expressly set forth in clauses (ii) and (iii) below, the SDC shall function solely as a forum for reviewing and exchanging information regarding the progress and overall direction of the TLR9 Agonist Trials and not as a decision-making body. The SDC shall meet in accordance with a schedule established by the SDC Chair (taking in consideration the availability of the SDC Representatives), but no less frequently than once a month during the Interim Period and as needed to address an Unresolved Issue as provided under clauses (ii) and (iii) below. Such meetings will occur via teleconference, videoconference or in-person, as determined by the SDC Chair. For an in-person SDC meeting held more than fifty (50) miles outside of Boston, Massachusetts, Merck will reimburse Licensor, in accordance with and subject to its corporate travel and expense policies, for the reasonable travel expenses incurred by Licensor's SDC Representatives in connection with their attendance of such meeting outside of Boston. The SDC Chair shall ensure that relevant results of such SDC meetings are recorded and approved by all SDC Representatives.

- (ii) A specific study team comprised of representatives designated by both Licensor and Merck will be formed in respect of each TLR9 Agonist Trial (each a "Study Team"). With respect to each TLR9 Agonist Trial, the applicable Study Team will be charged with certain decision-making responsibilities related to that Trial as set forth in the Trial's Charter Agreement. Each Charter Agreement will set out the procedures pursuant to which an unresolved issue, requiring the unanimous consent of the Study Team members, may be brought before the Strategic Development Committee (each an "Unresolved Issue"). In the event that the SDC Representatives receive written notice of an Unresolved Issue together with a summary thereof and the action to be decided upon (an "Issue Summary"), the SDC Representatives shall discuss the Unresolved Issue and shall meet with respect thereto if one or more of them believes a meeting or meetings to be useful. If the SDC Representatives do not resolve the matter within thirty (30) days following receipt by them of the Issue Summary (or such lesser or longer period as they may agree is appropriate for their discussions), then the SDC Chair shall, after due and reasonable consideration and subject to clause (iii) below, make the final decision regarding the Unresolved Issue unless such issue is a Safety Issue as defined below. In that case, Licensor's SDC Representatives shall, after due and reasonable consideration, including consultation with the safety team representatives assigned to the relevant Study, make the final decision regarding such Safety Issue. Licensor's SDC Representatives shall promptly inform the SDC Chair in writing of any final decisions regarding Safety Issues reached in accordance with this clause (ii). For purposes of this clause (ii), a Safety Issue is (A) any strategy decision regarding a TLR9 Agonist Trial (including a decision to terminate any such Trial) or material change to a TLR9 Agonist Trial protocol that is under consideration which arises from safety findings or other safety matters related to a Compound or (B) any change to a TLR9 Agonist Trial protocol that could reasonably be expected to significantly alter the foreseeable risks or discomforts to a TLR9 Agonist Trial subject. The SDC Chair shall provide the applicable Study Team written notice, with a copy to all other SDC Representatives, of any final decision regarding an Unresolved Issue reached by the Strategic Development Committee pursuant to this clause (ii).
- (iii) Notwithstanding any of the foregoing, the SDC Chair shall not make a final determination regarding an Unresolved Issue the implementation of which could reasonably be expected to have a material adverse effect on Licensor due to any liabilities or obligations under laws, rules or regulations applicable to Licensor as Sponsor of the relevant TLR9 Agonist Trial (a "Sponsor

MAE"). For purposes of the foregoing, (A) during the course of Strategic Development Committee discussions regarding an Unresolved Issue, each of the Parties should endeavor to discuss specific proposals to resolve the relevant issue and Licensor shall endeavor in good faith to identify any aspect of a proposal the implementation of which could reasonably be expected to result in a Sponsor MAE and (B) the Merck SDC Representatives shall provide Licensor written notice of any proposed final determination ("Proposed Final Determination") to be made hereunder ("Final Determination Notice") before its implementation. A Licensor's SDC Representative shall notify the Merck SDC Representatives in writing within five (5) Business Days of receipt of a Final Determination Notice if in Licensor's reasonable opinion, a Proposed Final Determination could result in a Sponsor MAE. In the absence of any such notice within such five Business Day period, the Proposed Final Determination shall become final and shall be implemented by written notification to the applicable Study Team. In the event a Licensor's SDC Representative delivers such notice with respect to a Proposed Final Determination, Merck shall not take any steps to implement the Proposed Final Determination and may submit to Licensor SDC Representatives another Proposed Final Determination that will be subject to this clause (iii).

3. Section 9.1, Indemnification by Merck, shall be amended and restated in its entirety as follows:

**9.1 Indemnification by Merck.** Merck shall indemnify, defend and hold Licensor and its Affiliates and each of the respective employees, officers, directors and agents (the "**Licensor Indemnitees**") harmless from and against any and all liability, damage, loss, cost or expense (including reasonable attorneys' fees) to the extent arising out of Third Party claims or suits related to (a) Merck's acts or omissions, during the Interim Period, in connection with the On-Going Trials or the Future Trials, (b) the Development, manufacture, use or Commercialization of a Compound, Follow-On Compound or Licensed Product by or on behalf of Merck, its Affiliates or Sublicensees, (c) the use, handling or storage of any Licensor Materials by or on behalf of Merck, its Affiliates or Sublicensees, (d) Merck's performance of its obligations under this Agreement, (e) breach by Merck of its representations, warranties or covenants set forth in this Agreement; provided, however, that Merck's obligations pursuant to this Section 9.1 shall not apply to the extent such claims or suits (i) result from the negligence or willful misconduct of any of the Licensor Indemnitees or (ii) arise out of a breach by Licensor of its representations, warranties or covenants set forth in this Agreement.

4. Section 9.2, Indemnification by Licensor, shall be amended and restated in its entirety as follows:

9.2. **Indemnification by Licensor**. Licensor shall indemnify, defend and hold Merck and its Affiliates and each of their respective agents, employees, officers and directors (the “**Merck Indemnitees**”) harmless from and against any and all liability, damage, loss, cost or expense (including reasonable attorney’s fees) to the extent arising out of Third Party claims or suits related to (a) Licensor’s acts or omissions, subject to the delegation of responsibilities to Merck or its Affiliates under any applicable Charter Agreement, in conducting the On-Going Trials or the Future Trials prior to and during the Interim Period, (b) the Development, manufacture, use or Commercialization of Compounds or Follow-On Compounds by or on behalf of Licensor, its Affiliates or licensees, (c) Licensor’s performance of its obligations under this Agreement, (d) breach by Licensor of its representations, warranties or covenants set forth in this Agreement, or (e) the matters set forth in [\*\*]; provided, however, that Licensor’s obligations pursuant to this Section 9.2 shall not apply to the extent such claims or suits (i) result from the negligence or willful misconduct of any of the Merck Indemnitees or (ii) arise out of a breach by Merck of its representations, warranties or covenants set forth in this Agreement.

5. Section 9.5, Insurance, shall be amended and restated in its entirety as follows:

9.5 **Insurance**. During the Interim Period and with respect to each TLR9 Agonist Trial, Licensor shall obtain and maintain, occurrence-form, product liability insurance with a clinical trials endorsement, or clinical trials insurance, in an amount that is agreed by Licensor and Merck as reasonable and customary in the United States pharmaceutical and biotechnology industries for companies engaged in comparable activities. Merck agrees to reimburse Licensor for the cost incurred by Licensor in obtaining such insurance, up to the amount set forth as insurance expense payable or reimbursable by Merck set forth in the applicable Trial Budget. After the Interim Period, until expiration or termination of the Term, each Party shall bear its own costs of obtaining and maintaining occurrence-form, product liability insurance with a clinical trials endorsement, or clinical trials insurance (including self-insured arrangements), in amounts that are reasonable and customary in the United States pharmaceutical and biotechnology industry for companies engaged in comparable activities. It is understood and agreed that this insurance shall not be construed to limit either Party’s liability with respect to its indemnification obligations hereunder. Each Party will, except to the extent self insured as permitted under this Section 9.5, provide to the other Party upon request a certificate evidencing the insurance such Party is required to obtain and keep in force under this Section 9.5. To the extent possible under each Party’s respective insurance plans, each Party will notify the other Party at least thirty (30) days prior to the expiration or cancellation of such insurance, or any reduction in coverage thereunder.

6. The Schedules to the License Agreement are hereby amended with the addition of Schedule 3.4(b) attached hereto.

7. All other terms and conditions of the License Agreement shall remain in full force and effect.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Parties have executed this Amendment as of the Amendment Date.

**Idera Pharmaceuticals, Inc.**

By: /s/ Louis Arcudi, III  
Name: Louis Arcudi, III  
Title: Chief Financial Officer  
Date: 11 Feb 2009

**Merck KGaA**

By: /s/ Dr. Claudia [illegible]  
Name: Dr. Claudia [illegible]  
Title:  
Date: 13 Feb 2009

By: /s/ Jens Eckhardt  
Name: Jens Eckhardt  
Title: Legal Counsel  
Date: 13 Feb 2009

Schedule 3.4(b)  
Strategic Development Committee Members

Idera SDC Representatives: [\*\*]

Merck SDC Representative: [\*\*]

Merck SDC Representative/SDC Chair: [\*\*]

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements (Form S-8 Nos. 333-3816, 333-3898, 333-3900, 333-3902, 333-34008, 333-71938, 333-116010, 333-116011, 333-116012, 333-126664, 333-137687, 333-137688, 333-147474, 333-152669, and 333-152670, Form S-1 as amended by Form S-3/A No. 333-136610, Form S-2 as amended by Form S-3/A No. 333-109630 and Form S-3 Nos. 333-111903, 333-119943, 333-126634, 333-131804, 333-133455, 333-133456, 333-139830 and 333-145556) of Idera Pharmaceuticals, Inc. and in the related Prospectuses of our reports dated March 9, 2009 with respect to the financial statements of Idera Pharmaceuticals, Inc. and the effectiveness of internal control over financial reporting of Idera Pharmaceuticals, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2008.

/s/ Ernst & Young LLP

Boston, Massachusetts  
March 9, 2009

**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**

I, Sudhir Agrawal, certify that:

1. I have reviewed this Annual Report on Form 10-K of Idera Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any changes in the registrant's internal control over financial reporting that occurred during the registrant's fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control and financial reporting.

/s/ Sudhir Agrawal

Sudhir Agrawal  
Chief Executive Officer

Dated: March 11, 2009

**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**

I, Louis J. Arcudi, III certify that:

1. I have reviewed this Annual Report on Form 10-K of Idera Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any changes in the registrant's internal control over financial reporting that occurred during the registrant's fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control and financial reporting.

/s/ Louis J. Arcudi, III

Louis J. Arcudi, III  
Chief Financial Officer

Date: March 11, 2009

**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**

In connection with the Annual Report on Form 10-K of Idera Pharmaceuticals, Inc. (the "Company") for the period ended December 31, 2008 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Sudhir Agrawal, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement has been provided to Idera Pharmaceuticals, Inc. and will be retained by Idera Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

/s/ Sudhir Agrawal

Sudhir Agrawal  
Chief Executive Officer

Date: March 11, 2009

**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**

In connection with the Annual Report on Form 10-K of Idera Pharmaceuticals, Inc. (the "Company") for the period ended December 31, 2008 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Louis J. Arcudi, III Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement has been provided to Idera Pharmaceuticals, Inc. and will be retained by Idera Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

/s/ Louis J. Arcudi, III  
Louis J. Arcudi, III  
Chief Financial Officer

Date: March 11, 2009